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Changes In Clinical Trials Mechanism Inevitable, But NCI Says It Will Heed Critics Of Proposals

The most drastic, far reaching changes in the way NCI supports extramural clinical trials have been placed on the table by the Div. of Cancer Treatment's Cancer Therapy Evaluation Program. Although CTEP Director Robert Wittes insists that "nothing is carved in stone" and "we don't intend to jam this down your throat," it is clear that

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In Brief

Cancer Control Month: Reagan Advises Americans To Stop Tobacco Use, Eat More Fiber, Less Fat

PRESIDENT REAGAN has been declaring April Cancer Control Month since he took office in 1981. He did so this year as a recovered cancer patient himself. Noting the great progress made in basic and clinical research, urging Americans to eat more fiber and less fat and to stop smoking and use of smokeless tobacco (probably a historic first for a sitting U.S. President), Reagan called on his countrymen to join in the effort to reduce cancer mortality 50 percent by the Year 2000. How about an NCI budget that provides the money meeting the Year 2000 goal requires, Mr. President? It's spelled out in the NCI Bypass Budget your Office of Management & Budget always ignores. . . . **DIAGNOSTIC TEST** that can detect the AIDS virus, rather than the antibodies as the current tests do, has been developed by Cetus Corp. The company said last week that it is using gene probe technology to identify the virus. The new test will be faster and far more accurate than the ELISA and Western Blot tests now in use. . . . **THREE CETUS** scientists have received the Inventor of the Year Award for their efforts in developing genetically engineered interleukin-2. David Mark, Leo Lin and Shi-Da Lu received $1,000 cash awards presented by the Intellectual Property Owners Assn. in a ceremony last week in Washington. . . . **STEVEN SCHULTZ**, vice president for administration and finance at Univ. of Texas System Cancer Center/M.D. Anderson Hospital, has been named executive vice president for administration. . . . **JOHNS HOPKINS** Medical Institutions have opened one of the nation's largest self contained magnetic resonance imaging facilities. It includes four MRI scanners, three of which will be used for research, the other for clinical diagnosis. Martin Donner is director of Hopkins' Dept. of Radiology.

Strategy Committees Causes Concern About Research Directed By Bethesda

(Continued from page 1)
NCI executives will insist, sooner or later, that substantive changes be made.

CTEP's rationale for the changes, based on a survey of clinical trials conducted over the past two years, was reported last week in **The Cancer Letter,** as presented at a meeting of cooperative group members and other clinical trials representatives. A general description of the proposed new organization and how it would work, followed by various options on reorganization of the cooperative groups, is described here:

1. Scientific prioritization.

Strategy committees for selected disease sites or therapeutic areas would be established to advise CTEP by setting forth in general terms national priorities for major phase 3 trials. In most cases cooperative groups would develop phase 3 protocols against the background established by the deliberations of the strategy committees.

For pilot trials, cancer centers and cooperative groups would continue to have broad discretion in deciding what pilot trials should be performed. This would ensure (CTEP said) preservation of scientific initiative within the groups, as well as free generation of new therapeutic approaches or hypotheses.

Participants in the meeting reflected the traditional concern of nongovernment scientists about "decrees" coming out of Bethesda on the type and nature of research which can be carried out. Wittes attempted to assure them that strategy committees would be dominated by the extramural community. Members would be investigators selected by CTEP, with concurrence of the DCT Board of Scientific Counselors, and would probably consist of the group committee chairmen in their respective areas, with ad hoc additions.

2. Trials organization--relation of groups to participants.

A cooperative group would have the flexibility to recruit participating investigators for individual studies, rather than being restricted to the standing members of the group. A group could then organize the participants in a study around the needs of the study, rather than organizing trials around the capabilities of the established membership.

Benefits, CTEP said, would be that this permits expansion or contraction of research agenda according to current needs; facilitates timely completion of trials; and minimizes the need to create new groups as new scientific opportunities arise.

It was this proposal that some at the meeting said would be "an administrative nightmare." They pointed out that DCT has been opposed to multiple membership in groups by individuals and argued that there are other ways to achieve flexibility.

3. Funding--reimbursement of participants.

Different kinds of contributions to a cooperative group would be reimbursed separately. In particular, reimbursement for accrual would be on a per case basis. This would replace the current system of institutional grants and would apply to a participant from any source (academia, community, HMO, etc.). Also, support for membership on group committees (writing protocols, analyzing results, etc.) or for performing group administrative functions would be provided separately.

This is the most controversial of CTEP's proposals, and Wittes acknowledged that it would have to be modified, perhaps into a system that would permit both institutional grants and per case payment.

4. Coordination--role of CTEP.

CTEP would coordinate the process, would integrate the priorities in the many areas of interest, and would represent the program in competition for resources within NCI.

CTEP went into more details on features of its per case reimbursement proposal.

1. (It would be) a one time payment to the physician investigator to reimburse the costs of entering a patient onto a clinical trial.

2. The rate of reimbursement should logically depend in some manner on major factors determining cost of data collection and followup (e.g., disease type, anticipated length of followup, number of modalities used in treatment, intensity of treatment). There will thus probably have to be two or three different per case rates.

3. Rates should also perhaps be permitted to vary by geographic region.

Advantages of a per case system would be: It would be a direct incentive to participants to maximize total accrual and accrual rates; separate contribution by accrual from other kinds of contributions; establish direct link between available dollars and

clinical trials activity, with groups and NCI paying for what they need and want; per case rate can be set at variable levels to include laboratory components of a trial.

Disadvantages would be the lack of institutional grants could detract from the credibility of group activities in certain academic departments; NCI would get fewer fringe benefits; and it could result in competition in per case rates with those set by industry.

CTEP listed features of a subcontracting system with a flexible relationship between the participants and the group.

Advantages: Groups could go where the patients are and where the medical expertise is for particular kinds of studies; a group would not be limited by the capabilities of its current roster of members and affiliates; they would have maximum flexibility for organization of a broad spectrum of trials, including nontreatment trials; it would facilitate use of the group system as a resource to all of NCI.

Disadvantages: Lack of fixed affiliation could produce problems with long term followup; the need to develop a group of participants around each trial would maximize organizational work for the group; simultaneous activity of multiple groups in the same institution may present problems in coordination within the institution; it could result in increased difficulties and perhaps costs for quality assurance.

One of the key features of the proposal is the flow of funds. Money from NCI to a group would go into a cooperative agreement for operations (headquarters) and for statistics. **There would be no institutional grants.** Support of the committee work of the groups, travel and other administrative group expenses would come out of the operations office.

Support for patient accrual would be via subcontracts from the operations office to individual investigators or to institutions. Release of these funds to the subcontractors by the group would be contingent on protocol approval by CTEP. The release could be front loaded so that investigators would have a financial base of some stability, provided that accrual is maintained. If accrual is not maintained, the stability vanishes.

CTEP said that under its proposals, operations and statistics offices would support and coordinate the conception, generation, execution, analysis and reporting of multicenter clinical trials and other kinds of studies consistent with the mandate of the group. They would arrange the optimal roster of participants for each clinical trial, by assuring representation of best possible physician expertise and access to patient numbers.

Groups would be reviewed by the Cancer Clinical Investigation Review Committee of NCI's Div. of Extramural Activities, as they are now, through grant applications. Support would be through cooperative agreements, also as is done now.

Group committees would have two purposes: (a) In areas that are covered by the strategy committees, to develop phase 3 protocols against this background. Under most circumstances, protocols should be responsive to the priorities of the committees; (b) in areas not covered by the strategy committees, to develop protocols, as they do now. Of necessity, these protocols would compete for funds with those from (a), with each other, and with pilot studies within the group system.

Participants, physicians with the necessary expertise and access to patients needed for a particular trial, would be selected by group leadership and committees. They would be reviewed by the CCIRC at the time of the grant application, and by CTEP at the time of protocol review of individual studies. Basis for review would be accrual potential, individual qualifications and quality of data. The award would be through subcontracts from the operations office.

CTEP said its role would be coordination of the program as a whole; integration of the priorities from the many disease and development areas; more widespread concept review of proposals, before protocols are written; coordination of protocol review, which might involve peer review, program staff review, or both depending on the type of study; and "defense of the clinical trials program in NCI's budget wars."

CTEP listed five options for the overall structure of the group system.

Option 1: The present structure, with modifications. Groups approved by peer review with fundable priority scores would continue. Research focus and agenda could be expanded or contracted as needed.

Option 2: One enormous grop that can do everything. "We're not really considering this," Wittes said.

Option 3 (a): One group for each broad class of clinical problem--pediatrics, adult surgical and surgical adjuvant, adult solid tumor advanced disease, adult hematology, adult radiotherapy.

"My feeling is this is what we would do if we were starting all over again," Wittes said.

Option 3 (b): Two groups for most classes of clinical problems--two pediatric groups, two each for adult surgical and surgical adjuvant, adult solid tumor advanced disease and adult hematology, and one adult radiotherapy.

The two group for each category addresses what Wittes said was an "overwhelming" disadvantage of Option 3 (a)--each group would be a monopoly.

Another advantage of 3 (b) is that it would be closer to what the structure of the present system will likely be after the current review cycle, something "that has not escaped our attention," Wittes said. Seven of the last eight groups reviewed by the CCIRC have either been disapproved or given an unfundable priority score.

Option 4: Reorganize by disease or disease group. The result would look like an expanded version of the disease oriented segment of the present cooperative group system, e.g. thoracic, head and neck, GI, GU, breast, hematology, melanoma/sarcoma, neuro-oncology, pediatrics.

Option 5: Reorganize by geographical region. Targeted regions could be either a few "mega ones" such as southwest, southeast, northwest, northeast, or a larger number that have some geographical identity. Pediatrics and developmental radiotherapy would remain national.

Miscelaneous implications of the proposal.

Since a single institution may be participating in the affairs of several groups, individuals in the same institution may hold subcontracts for individual studies. The groups would have much more flexibility than now but would also have a greater administrative burden in organizing studies and in accounting. CTEP acknowledged that NCI would have to support that.

The need for common toxicity criteria, response criteria and reporting formats would be greater than ever.

Advantages and disadvantages of the options and further discussion of them will be reported next week in The Cancer Letter.

MAOP Intends To Continue Operating With Private Funds, Drugs From NCI

The Mid-Atlantic Oncology Program was one of four regional cooperative groups supported by NCI, prior to the "March slaughter" of three when the Cancer Clinical Investigation Review Committee disapproved their grant renewals (**The Cancer Letter,** March 28). The other two were the Northern California Oncology Group and the Piedmont Oncology Assn.

The fourth, the North Central Cancer Treatment Group, will be reviewed by CCIRC in the next cycle.

Some of the large cooperative groups have regional names but are really national in scope (At the recent Assn. of Community Cancer Centersmeeting, Southwest Oncology Group Chairman Charles Coltman commented that, as it is with "non Hodgkin's lymphoma and non small cell lung cancer, we're a non southwest group").

Regional groups were encouraged in the late 1970s by then Div. of Cancer Treatment Director Vincent DeVita, who saw them as a means of extending clinical trials into community hospitals and to help fill gaps in areas of the country where the larger groups were not operating to any significant extent. That was before the advent of the Community Clinical Oncology Program. DeVita had been encouraged by the success of NCCTG, headquartered at Mayo and chaired by Charles Moertel.

Moertel, at the ACCC meeting, reviewed accomplishments of his group and added in reference to the fate of the other three regional groups, "If anyone is going to try to do us in, they're going to have to show me who is doing any better."

MAOP likewise is not ready to throw in the towel. "We absolutely want to keep it going, and we intend to," MAOP Chairman James Ahlgren told **The Cancer Letter.** MAOP is going to try to do it the old fashioned way, with nongovernment money.

Seeing the handwriting on the wall well before the CCIRC's action, MAOP formed the Mid-Atlantic Cancer Research Foundation and started making fund raising plans. John McCabe, development director for Mercy Hospital in Scranton, was named to the same position for the foundation, with his salary supported by the Sisters of Mercy.

So far, the foundation has obtained more than $250,000 in pledges, $70,000 from MAOP

members. MAOP's NCI support totaled about $700,000 a year, including overhead, so the foundation still has a way to go before getting back to its full operating level.

"We'll have some severe belt tightening for a couple of years," Ahlgren said. "But everyone wants to do it." Most members will forego overhead and pay their own travel costs during the lean times.

"We know we're doing good science, which will come to fruition soon," Ahlgren said. NCI's Cancer Therapy Evaluation Program is supportive of the effort and will continue to supply investigational drugs and protocol review. "CTEP considers us an important resource of the National Cancer Program."

NCI Says More Phase 4 Trials Needed In Prevention, Nutrition

NCI wants to encourage more Phase 4 studies in the areas of prevention and defined population studies, Knut Ringen, special expert with the Div. of Cancer Prevention & Control, told the recent joint meeting on advances in cancer control of the Assn. of the Assn. of Community Cancer Centers and the Assn. of American Cancer Institutes. "NCI would like to see more Phase 4 studies, especially prevention" trials, he said. Another area of special interest to NCI is the addition of more defined population studies, particularly in nutrition.

NCI is currently trying to develop "more responsive reviews" in hopes of encouraging more investigator initiated applications, he told the meeting. Ringen chaired one of three panels in a day long session on advances in cancer control at the meeting.

Discussing the papers presented at the meeting, Ringen said he found the move toward more rigorous research in the area of how to deal with hard to reach populations very encouraging. He told the meeting that "it's very important to see [investigators] using applied epidemiology more effectively than before."

Papers presented at the session included a test of two programs for worksite smoking cessation. Smokers and their interest in participating in smoking cessation programs were identified through an employee health survey. Two programs in two modalities, plus control groups, were used.

One three week program, MCP, focused on initial cessation, whereas the second, RPP, concentrated on relapse prevention as well as initial cessation over an eight week period. Smokers interested in quitting were invited to participate in the modality of their choice, a small group or a self help format.

A total of 402 subjects were randomized to MCP, RPP, or a control group that received a minimal American Cancer Society intervention, within the two modalities.

In the group quit modality, MCP produced higher initial quit rates than RPP, 61% compared to 37%, respectively. By the three month followup, however, relapse rates were higher for MCP. Differences were smaller between the programs in the self help modality, but the trend was the same.

Two of the researchers involved in the study, Beti Thompson of the Fred Hutchinson Cancer Research Center, and Mary Sexton of the Univ. of Maryland Medical School, presented an overview of employee reactions to worksite smoking policy changes at the meeting's poster session as well.

The study found that only a small minority of employees overall are opposed to a worksite smoking ban. The findings appear to contradict the commonly cited objection that restricting smoking could have a negative effect on employee morale.

In the study, 4,955 of the 9,000 employees at a high tech company were surveyed to assess their reactions to a new smoking policy. The new policy limited smoking to only a few places at the worksite.

Overall, the majority of employees, 69.6%, favored the new policy. Another 17% did not care about the new policy. Only 9.8% of employees surveyed were opposed to the new policy.

The majority of smokers either favored the new policy (25.4%), or didn't care (30.4%). Less than half of the smokers, 40.3% , were opposed to the new policy. Ex-smokers were more likely to be opposed to the policy than never smokers, 5% compared to 2.3%.

Other variables that correlated with differences in reactions to the policy included education, job stress, health practices, age, and gender. Pack years and total time since quitting were associated with reaction to the policy for former smokers. Current smokers' reactions to the policy were associated with the desire to quit, the previous number of quit tries and pack years.

"The most significant finding from this study is that only a small minority of

employees overall are opposed to a smoking ban at the worksite suggesting that employers, in the interests of reducing health hazards and also for economic reasons, should be encouraged to implement policies that restrict smoking at the worksite," the paper concludes.

Another paper on cancer control and the workplace focused on the knowledge and practice of cancer control technologies among workers at increased risk for certain cancers. A three year study was funded by NCI, the International Rubber Workers Union and the Univ. of North Carolina. The evaluation and demonstration project was designed to assess and increase workers' knowledge and practice of cancer control technologies.

Workers in the rubber manufacturing industry "bear a disproportionate amount of the cancer risk due to workplace exposures," the paper says. For example, tire builders have 4.1 times the risk of brain cancer than the general population.

The paper notes that "experts agree that most, if not all of the occupational cancer deaths are preventable through a combination of three types of controls: hazard containment, control of hazard transmission and worker protection."

The study surveyed 1,777 workers from 23 plants about their knowledge and work practices relevant to cancer risks.

"Baseline data reveal an alarming need for the diffusion of cancer control information and technologies to the average floor worker." The survey found that more than one third (39%) of the workers required to use personal protective equipment such as gloves, do not consistently use them. One half of those required to wear protective clothing such as coveralls do not always do so, either.

According to the paper, "data on engineering control technologies are even more alarming." For example, 69% of the workers reported that they are not sufficiently informed about how to check to insure that the available engineering controls are working properly.

The paper was authored by Arnold Kaluzny, Anna Schenck and Godfrey Hochbaum, UNC, and Louis Beliczky and Michael Krueger of the United Rubber Workers Union.

Marketing cancer information to communities that underutilize cancer information systems was the goal of an intervention and control study of a newspaper feature conducted by researchers at Dana Farber Cancer Institute in Boston.

A 1982 analysis of call rates for Massachusetts cities and towns to NCI's toll free Cancer Information Service revealed a statistically significant correlation between the "Boston Globe" circulation and call rates. The significant relationship remained when controlling for other highly correlated factors including percent college educated, median income, and percent Spanish origin.

The CIS based at Dana Farber is promoted in several ways, including the Cancer Information Column; a question and answer newspaper feature prepared for the Sunday Globe. Ten newspaper media markets with low CIS call rates and low Globe circulation rates were identified. The Cancer Information Column was then marketed and accepted for publication in five newspapers, with the remaining five media markets serving as a comparison group.

The CIS call rate increased 117% in the intervention group in a comparison of the two nine month periods pre and post intervention. The CIS call rate increased 68.3% for the control group and 71.1% for all other Massachusetts communities during the comparison period.

The paper notes that "the changes seen in control and all other Massachusetts communities are comparable and may be attributed to NCI initiated promotions."

The larger percent change for the intervention group, however, "is statistically significant and can be attributed to the intervention."

The paper was authored by Carey Azzara, Kate Duffy, Susan Oehme, Elizabeth Mallon and W. Bradford Patterson.

A survey of members of the American Assn. of Cancer Institutes and ACCC found that 60% offer one or more cancer control services.

Of 314 members surveyed, 204 (65%) responded to the survey of current cancer control service and research activities, their target populations, funding sources and expected level of funding over the next five years.

Of the 122 (60%) of responders who offer one or more cancer control activities, more than 18% conduct only research, while 26% provide only cancer control services. Some 797 service activities were offered to target populations by 100 programs, for an average of eight per program. Of those programs, 27%

are prevention services, 29% screening and detection services, 28% diagnostic and treatment services, and 17% rehabilitation and continuing care.

Ninety one programs conduct 479 research studies, for an average of five studies per program. Of those 479 studies, 25% deal with prevention; 22% deal with screening and detection; 35% concern diagnosis and treatment and 18% regard rehabilitation and continuing care.

The paper was authored by Zili Amsel, Paul Engstrom, Barbara Rimer, Martha Keintz and D. Gillespie.

Community Health Promotion Grants Available From Kaiser Foundation

Cancer is one of five major health problems targeted for community grant funding by the Henry J. Kaiser Family Foundation as part of its new health promotion program. The foundation has established a Community Health Promotion Grant Program that will provide communities with three to five year grants of up to $150,000 per year. The program seeks to foster community based approaches to address one or more of the five major preventable causes of morbidity and mortality in the U.S.: cardiovascular disease, substance abuse, adolescent pregnancy, cancer and injuries.

In order to be eligible for a grant, a community must form a health promotion council that includes representatives of educational institutions, business, labor, media and religious organizations, voluntary health agencies, health care providers and public service groups. The council will identify the community's major health problems to be addressed and develop a plan to address that problem. Other problems can be added later.

Only communities from the 13 Western states will be eligible for an award under the initial grant cycle. The foundation does plan to expand the program to the rest of the country, but has released no timetable for the expansion. Communities will be required to match funds granted by the foundation with those obtained from community foundations, corporations or other contributors.

Priority will be given to programs with one or more of the following characteristics: They focus on the external factors or the surrounding influences that have a major impact on health related behaviors, as well as on the specific behaviors themselves; they pay special attention to the poor, whose skills and opportunities for choosing healthy habits are limited; and they develop promising intervention methods and programs that can provide a model for other communities.

Examples of community based projects that might be supported in the foundation's program include tobacco, alcohol and drug abuse prevention programs for junior and senior high school students, or an education and social support project to reduce adolescent pregnancy.

A community is defined as "a public health unit that may be as small as a neighborhood or as large as an entire city."

The deadline for receipt of letters of intent is May 12 for communities in the 13 Western states. The deadline for completed applications is Sept. 5. The foundation will send out application packets in early June, visit sites in October and November, and make the first grants in April of 1987.

A workshop for community representatives will be held at the Health Promotion Resource Center at Stanford Univ. July 17-19 to aid potential applicants. Other workshops are planned in other regions of the country as the program is expanded.

The community health promotion grants are one element of a new Health Promotion program underway by the foundation. The second element is the establishment of the Health Promotion Resource Center at Stanford. Stanford has received $307,198 for six months to develop the center, and will receive additional grants to support its operation over the next several years.

That center will provide training for volunteer and staff health promotion workers in each grantee community, give technical advice on initiating and developing community base projects; and develop print, radio and tv materials for use in the communities.

The third aspect of the program is a national public information and education program that addresses "both the individual determinants of health behaviors and the surrounding influences that contribute to preventable diseases and untimely deaths," Wendy Watson, program director, told a press conference in Washington.

The major goals of the public information and education program are to increase public awareness of the five major health problems and their causes; to identify specific

changes in individual behaviors and surrounding influences that can help solve these problems; to increase public support for health promotion efforts; and to stimulate public discussion of the role of prevention in the nation's overall approach to health.

Address letters of intent or inquiries about the grants program to Wendy Everett Watson, Sc.D., Program Director, The Community Health Promotion Grant Program, The Henry J. Kaiser Family Foundation, 525 Middlefield Road, Suite 200, Menlo Park, Ca. 94025.

Counseling Significantly Reduces Cancer Pain, Fox Chase Study Shows

Cancer patients who receive counseling on pain management experience significantly less pain than patients who do not receive any special counseling or materials devoted to pain management, according to a paper presented by Barbara Rimer of Fox Chase Cancer Center at the recent meeting of the Assn. of Community Cancer Centers.

The intervention consists of specifically tailored printed materials and a counseling session with an oncology nurse. The counseling advises patients when to take pain medication and how to avoid side effects, with both the counseling and written elements of the intervention designed to be clear, concise, and personalized and to provide specific action instructions. To date, 185 patients have been accrued in the study, which will involve 250 patients. Data on 156 patients has been analyzed.

Cancer patients with pain other than post surgical pain are randomized to receive or not receive the intervention. Of the first set of patients, the majority had colorectal, lung or other cancer, such as prostate and lymphomas. The majority had metastases, 44% distant and 36% regional, with 20% of the patients studied having no metastasis. The mean age of patients studied was 62. Half of the patients had less than a high school education, 70% were married, and 20% widowed. No differences were noted between the two groups when pretests were administered.

Patients who were randomized to the no intervention group received the "usual standard of care" regarding pain management that they would normally receive from physicians and nurses.

Patients were followed up by telephone one month after initial contact in order to assess the impact of the intervention.

The major foci of the intervention were to lessen patient and family concerns about addiction and tolerance to pain medications, and to increase patients' compliance with pain control regimens.

The most common pain medications prescribed to the study patients were Dilaudid (25%) and Percodet (43%). At the time of the first contact, 60% of patients knew the names of their medications. While 60% of the patients reported variable pain, 40% of them had pain all the time. More than half (55%) of the patients said they had been told about the side effects of pain medication.

One month after the intervention, subjects in the experimental group were more likely to take their medication at the correct frequency. The intervention group was also significantly more likely to take the correct dosage ($p=.03$) and to recall being told how to take the medicine ($p=.03$).

Rimer reported that the patients in the intervention group also seemed to be less worried about side effects from medication, and knew what actions to take in order to prevent side effects. The intervention group also seemed to feel more in control of their pain than the control group did at one month followup.

Following the post test interview, patients in the control group are offered the booklet on pain management.

Rimer cites estimates that 60% to 90% of cancer patients experience pain at some time, but notes that "much of this pain remains poorly controlled." She suggests that poor pain control "may have its origins not only in the disease process itself but also in patient and physician behaviors."

The study also suggests that there may be sociodemographic variations in pain. If those differences persist, they should be considered in matching patients and intervention strategies, she said.

The Cancer Letter _Editor Jerry D. Boyd Associate Editor Patricia Williams

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