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Gonorrhea Vaccine Trial To Proceed

By Nancy Tomich

WASHINGTON—A gonorrhea vaccine developed jointly by Walter Reed Army Institute of Research and the University of Pittsburgh will undergo its first clinical trial early this year.

The vaccine, which has been "in the bottle" for a year and a half, will be tested among 5,000 Army, Navy, Air Force and Marine volunteers stationed in Korea in a double-blind, randomized placebo study.

Half the group of volunteer subjects

will receive the vaccine in two doses of 100 micrograms each, given two weeks apart. The other half will be injected with a placebo.

The study subjects will be monitored for eight weeks, according to a Defense Department source familiar with the protocol, after which each will be cultured.

When the study code is broken, the source related, it hopefully will be possible to tell whether the vaccine conferred protection against gonorrhea, which is a local infection of the genital area.

This will be accomplished simply by determining who has an infection and who does not, and whether these individuals received vaccines or not.

"We won't know if anyone has been exposed to the disease," the source related. "In fact, we will be discouraging these people from going out and having sex. No one would recommend they do that."

"We firmly expect the rates of sexual

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Electronphotomicrograph of *Neisseria gonorrhoea*.

Congress Redirects Funds

Expansion Of COMISS Halted

WASHINGTON—As it wound up a marathon session designed to keep government operating, Congress last night passed language prohibiting the expansion of the Veterans Administration's COMISS pharmacy system.

In a continuing resolution passed at the 25th hour—too late to prevent agencies from shutting down for a few hours on December 20—Congress extended funding for all agencies for which regular appropriations bills had not been passed.

Although an appropriations measure had been passed for the VA, language halting COMISS was placed in the continuing resolution, or "CR," as it was referred to in those final days of the 97th Congress, by the House Appropriations Committee, whose members directed that decentralized field-developed modules be expanded instead.

This language was accepted by both the full House and Senate, meaning the COMISS system now is limited to the Chicago-area hospitals in which it already is operating.

In adopting the CR, which extends until September 30, 1983, Congress also lifted the pay cap for federal executives. Pay for members of the Senior Executive Service now will rise to a ceiling of \$67,200 from the current one of \$58,500.

For employees in the GS 15 step 7 level through GS 18, who have been capped at \$57,500, the ceiling now rises to \$63,800, an increase of 11 per cent.

In VA, there was question whether physicians would receive the entire 11 per cent increase or none of it.

An "option paper" was being circulated within the agency to obtain viewpoints as to whether physicians should



be given the entire increase on top of the special pay they now receive, have their special pays adjusted in proportion to the full amount of increase in base pay or be given an amount of increase that falls somewhere in the middle of these two extremes.

VA Follows Mid-Course On MD Pay

WASHINGTON—Faced with a tedious balance between physician morale and relentless waves of White House fiscal conservatism, the Veterans Administration has taken a middle road—giving doctors more money, but not as much as it might have.

The new formula officially was signed into policy two weeks before Christmas, offering relief to thousands of physicians in the upper pay grades who, because of a variety of federal policies, earlier had been denied the full 4 per cent pay raise for federal workers the President announced in October.

The VA decision, which was made retroactive to October, when the current fiscal year began, could cost the agency \$21 million, or \$13 million more than the minimum needed to meet the new legal requirements of the President's 4 per cent raise for federal workers.

The cost became particularly impor-

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Agent Orange: Exposure 'Tackled'

Soldier's Dosage Calculated By DoD Formula

By Terry Jemison

WASHINGTON—Finishing touches are being integrated into a Defense Department plan for gauging ground troops' exposure to agent orange, a formula that has been under refinement for a year.

Bart Kull, co-chairman of a high-level interagency work group on agent orange appointed by President Reagan, said the group has set up a science subcommittee specifically to coordinate the refinement of the government's leading plan, or "concept paper," for calculating exposure.

The Agent Orange Working Group was scheduled to meet in mid-December, and a Defense Department source said the methodology for estimating agent orange exposure was "just about hammered out."



The DoD formula has yielded a quantitative dose estimate for the soldier in thick jungle, directly under a Ranch Hand run: a maximum dose of .0010752 ounces of agent orange per soldier.

The most controversial part of the DoD concept paper for the major ground troops study is a three-tiered system proposed to choose cohorts of high (or low) exposure based on battalion location.

"Because of the concerns expressed by the Veterans Administration and

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CDC Now Faces Challenge Of Cohort Selection

WASHINGTON—A ticklish task of defining exposure to agent orange soon will officially rest on the shoulders of scientists at the Department of Health and Human Services.

It is a question that was not so critical for the first federal epidemiological study already begun, that involving the Air Force Ranch Hand Unit, a clearly defined population of flight crews that sprayed the herbicide over Vietnam jungle and cropland.

Now, attention is turning to a new and much larger study of the ground troops who were underneath the jungle canopy.

After HHS officials said at a hearing in September they could have proceeded with a health study of Vietnam ground troops faster than the Veterans Administration has acted to design one, key members of the committee moved to let them prove it.

A letter from the House Veterans Affairs Committee convinced VA to relinquish management and supervision of the retrospective cohort study.

When an interagency agreement is signed this month, it will be up to an HHS agency, the Centers for Disease Control, to resolve the question of exposure.

CDC must decide if the current plan for study subject selection according to exposure, recently criticized by the National Academy of Sciences, will be modified at all—or retained at all.

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Corps Changing

The legislation authorizing the National Health Service Corps expires at the end of 1983. Program director Billy Sandlin predicts the corps will replace its scholarships with loans or other mechanisms. Report, page 2.



Formula To 'Calculate' Agent Orange Dosages

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many members of the (working group) science panel as to the precise methodology for the selection of cohorts, a moratorium on the actual selection process for the pilot study (to test methodology) was requested pending refinement of a valid methodology," Kull said.

Kull, an intergovernmental affairs specialist at the agency that has lead responsibility for managing the working group, the Department of Health and Human Services, said the working group's concerns were similar to those expressed by the National Academy of Sciences (see related story).

The review, he said, will not impede selection of cohorts, but the refined methodology will assure "valid, reliable, timely and relevant data that veterans can trust will produce reliable answers on this vital issue."

One question looming over application of the exposure estimation plan in an epidemiological study is the potential confounding influence of the general United States population's exposure to agent orange components.

Scientists are concerned about veterans' earlier domestic exposure to dioxin, the toxic chemical federal scientists have determined to be carcinogenic, teratogenic and fetotoxic in some animals and which has been implicated as the likely villain in any long-term agent orange health effects.

Agent orange was a 50-50 mix of two herbicides, the chemicals 2,4-D and 2,4,5-T. It is the latter whose manufacturing process inadvertently introduces dioxin as an impurity into the herbicide.

Over 30 years, the herbicide 2,4,5-T grew into wide use in American agriculture, the forest industry, and even as a popular lawn chemical used by home gardeners, such as in "weed-and-feed" fertilizer mixtures sold at the corner hardware store.

The architect of the much-touted agent orange exposure estimate methodology, Jerome G. Bricker, PhD, speculated in a report on his model for the major ground troops study, "It may be impossible to find any group of persons who have not had some exposure to dioxin if they are older than 10 years."

Dr. Bricker has estimated the typical agent orange exposure rate at the "ground zone," from the ground up eight feet into the jungle, as 0.166 gallons per acre.

However, in the U.S., the customary agricultural use—before a 1970 ban—was a rate of two gallons per acre, according to Dr. Bricker's report, which has become the cornerstone for estimating exposure accepted by the Cabinet-level work group on agent orange.

Dr. Bricker said there actually are three methodologies under development. Kull said there is a "misunderstanding in some quarters" that they are designed to be interchangeable, but they actually are separate and are designed to meet different needs for different studies.

Dr. Bricker, health legislation specialist at the Defense Department, is a DoD emissary to Kull's interagency working group.

The powerful defoliant 2,4,5-T largely was phased out of American agriculture between 1970 to 1979 by the Environmental Protection Agency, which has canceled registrations for most such uses.

In 1980 regulatory actions to formally cancel commercial 2,4,5-T permits, the EPA determined there is a reasonable basis to conclude that humans are likely to experience effects comparable to TCDD's carcinogenicity in mice and rats.

Veterans Administration officials, faced with potential compensation costs of billions of dollars, have been cautious in such extrapolations and insist that only positive data from studies specifically of humans can validate that theory.

The Bricker exposure estimate of .166 gallons per acre for Vietnam ground-level concentrations is an estimate assuming several factors that were not always present, such as dense, triple canopy jungle.

If an area had been sprayed earlier, and the exposure in question were to involve a re-spraying mission, the absence of foliage (due to the first treatment) would increase the proportion penetrating down to the 8-foot zone.

According to the Bricker report, troops under "sparse canopy or relatively open forests" might have gotten a dose of agent orange of up to .0181 ounces per soldier. In the dense jungle setting, that dose was estimated at a maximum of only .0010752 ounces per soldier.

In a memorandum to the science panel explaining his calculations, Dr. Bricker assumed that the agent orange probably had a 2 parts per million concentration of dioxin (TCDD).

With only about .0005376 ounces of agent orange per square foot reaching the 8-foot ground zone, Dr. Bricker said, "five ten-thousandths of an ounce per square foot is a very small amount if it contained 2 ppm of TCDD."

Other variables and influences in soldiers' exposure to agent orange in Vietnam have been identified by Dr. Bricker:

• There is no way to estimate dosage from the inhalation of the airborne droplets of herbicide, each smaller than 300 micrograms.

• Agent orange was "utilized in considerable quantities around bases and along lines of communication."

Less rigidly controlled than Ranch Hand UC 123 missions, helicopters often sprayed the herbicide at low altitudes in areas cleared of high trees, increasing exposure concentration due to rotor blade downwash, lack of tree foliage absorption and close proximity to troops.

Such helicopter spraying not only included camp perimeters but armored personnel carriers and guard towers.

• Other spraying was done from trucks and with finely atomizing backpack sprayers. Fire base perimeters were sprayed about every five weeks with the spray frequently drifting back over population centers with "a much closer and far more concentrated exposure to herbicides than for troops under a dense jungle canopy being sprayed by C123 aircraft," Dr. Bricker said in his report.

• At low altitudes, the Ranch Hand flights occasionally would jettison the herbicide under low emergency conditions, which could create a ground exposure rate 500 feet below of as much as .1424 gallons per foot.

The emergency jettisons, which were announced by Health and Human Services secretary Richard S. Schweiker in September, 1981, when he learned of them, would make a good component of the criteria for selecting ground troops

for the VA epidemiological study, Dr. Bricker said.

However, the first criterion for selection of the exposed cohort would be close proximity to Ranch Hand sprayings. Ten battalions in the spraying areas on multiple occasions could yield 24,000 personnel, and the VA had anticipated needing a "highly exposed" cohort of only 12,000.

CDC plans for the size of the study cohorts have not yet been determined.

In what Dr. Bricker calls "step 2 criteria," the records of the base camps and fire bases occupied by each of the 10 battalions would be reviewed in detail to determine when camp perimeters were sprayed with agent orange during a one-year period.

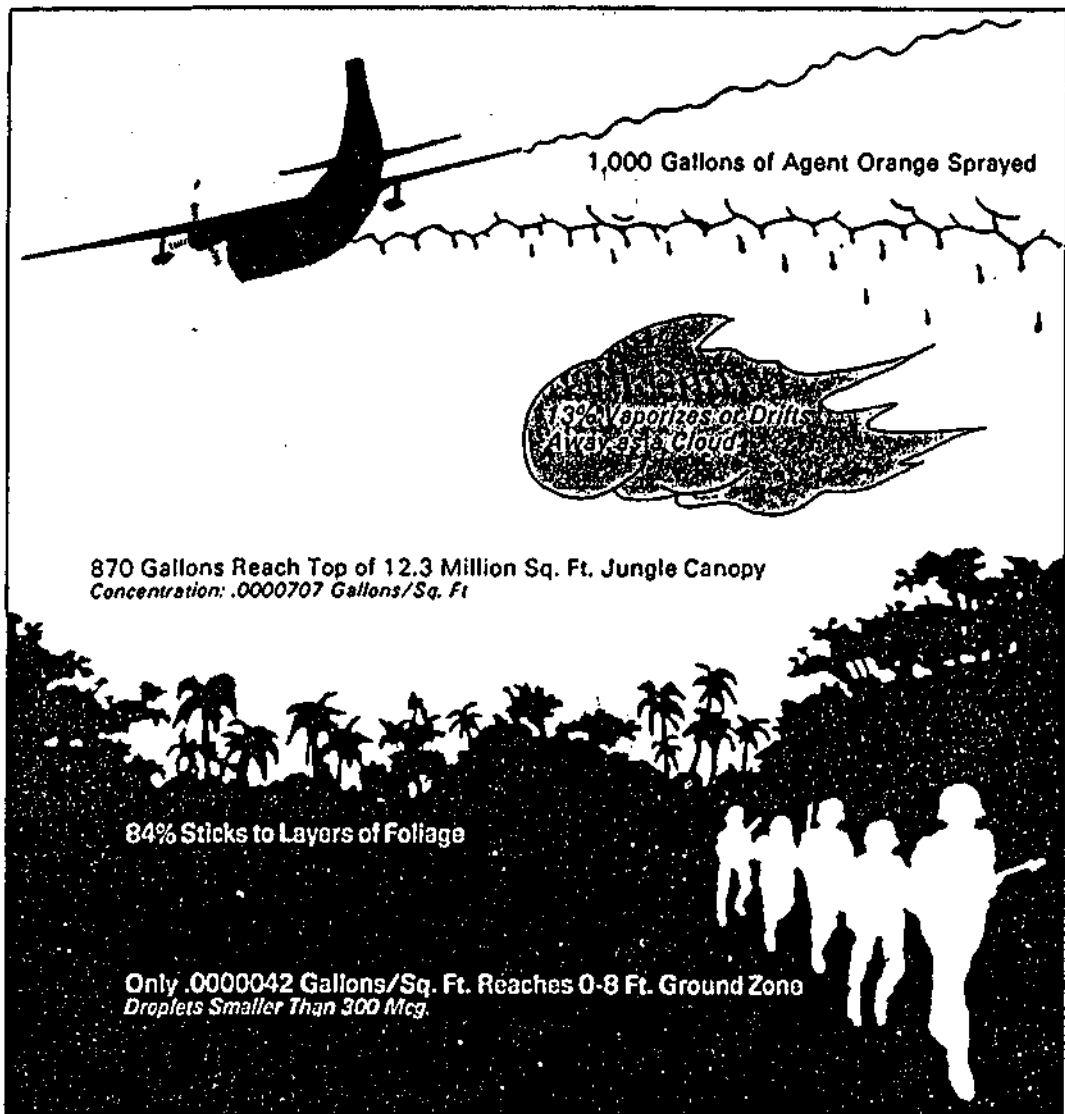
Those battalion-size units meeting both step 1 and step 2 criteria would be examined for a third criterion, that units of the battalion were encamped or operating within 2 km. of one of the low altitude jettisons.

Similarly, Dr. Bricker proposed using the criteria to test for the "proposed unexposed Vietnam combat cohort."

Ten battalions whose units operated exclusively in non-sprayed provinces would be selected, again in hopes of a total troop complement of 24,000 soldiers.

After selecting units not meeting "criterion 1," or proximity to Ranch Hand Unit spraying, the second criterion also would be applied in reverse—finding units not exposed to any local perimeter herbicide spraying.

The third criterion in reverse, not being located near where loads were jettisoned in emergencies, is easier to meet, he said, since those provinces were not in the heavy combat spray area.



An interagency working group on agent orange is refining a "concept paper" calculating ground troops' exposure that includes this Defense Department exposure estimate. The concept paper, authored by Jerome G. Bricker, PhD, assumes this dose at the "ground zone" from a C123 Ranch Hand aircraft flying at 150 knots and 150 feet altitude.