CHAPTER III

Organization, Methods, and Physical Factors of the Study

Organization and Methods

In 1959, when the study was designed, one central question seemed unanswered. As stated in the protocol governing the study, that question is whether ". . . the use of direct ultraviolet radiation in operating rooms, throughout the course of the operative procedure, will afford a significant diminution in the incidence of wound infection." It was recognized 1) that this question could be investigated only by comparing patients operated on under ultraviolet radiation with those operated on without such radiation; 2) that the trial must be organized so as to minimize opportunities for bias to enter the comparison; 3) that the trial must be large enough to have a high probability of attributing benefits to ultraviolet radiation if, indeed, such benefits exist; 4) that the institutions and clinical material must be sufficiently representative of the total surgical experience to permit generalization; and 5) that the intensity of ultraviolet radiation throughout the operating room must be at a level considered effective by its advocates. It was also recognized that any beneficial effect of ultraviolet radiation might be confined to clean wounds, so that considerations of sample size should refer primarily to such wounds.

An unbiased comparison of ultraviolet radiation and ordinary illumination of the operating room was sought by means of an initial random allocation of patients to operating rooms with and without ultraviolet radiation, and by a double-blind restriction on observations as to the use of ultraviolet radiation and its possible relationship with any subsequent infection. In this way, the two treatment groups were made quite comparable with respect to the many factors that might influence the occurrence of infection, and the observer of subsequent infection was not to be prejudiced by his knowledge, or the patient's, as to the specific situation of the operating room at the time of operation.

Because it seemed impractical to randomize individual patients and surgical teams, the unit of randomization selected was an individual operating room for a period of seven consecutive days. A randomization schedule was then evolved, assigning these operating-room-week blocks to either an ultraviolet or a control status, subject to two additional restrictions: 1) no operating room might remain unchanged in status longer than three weeks; and 2) at any one time, in each hospital, the number of irradiated operating rooms should equal the number unirradiated, insofar as possible. Only the statistician responsible for the schedule and the engineer at the individual hospital had information as to this schedule. It may be noted that this pattern provides for an unbiased treatment comparison not only within each hospital, but also within each operating room.

To ensure a broad representation of surgical experience, five university hospitals were enlisted in the effort. This number lessened some of the administrative and scientific difficulties of a large group of hospitals, and yet was large enough to provide the necessary clinical experience within a three-year period. It was calculated that 5,000 clean wounds (half control) would be needed to give a probability of 90 per cent of finding in favor of ultraviolet radiation if, indeed, ultraviolet ir-

Table 1. Summary of Reports Dealing With Use of Direct Ultraviolet Irradiation in the Operating Room

Author	Types of operations	Irradiated				Unirradiated (controls)			
		Total operations	Period	Wound infections		Total operations	Period	Wound infections	
				Number	Percent			Number	Percent
Hart (1960)	Clean; general surgical, orthopedic and neurosurgical; including 187 reopened thoracoplasties	2600	1936-41	15	0.6	1313 469	1931-36 1936-41	207	11.6
Overholt and Betts (1940)	Clean; thoracoplastic	411	1937-38	11	2.7	29	1936	4	13.8
Woodhall et al. (1949)	Clean; neurosurgical	2753	1945-48	10	0.4	2275	1942-45	25	1.1
Woodhall et al. (1949)	Clean; neurosurgical	3019	1938-48	42	1.4	--			
Kraissl et al. (1940)	Clean; major general surgical	52	1937	1	1.9	--			
Robertson and Doyle (1940)	Mostly clean; pediatric	41	1936	1	2.4	--			

radiation does result in a reduction in the postoperative infection rate from an estimated 5 to 3 per cent, and if statistical tests were made at the significance level .01.

Few restrictions were placed on the clinical composition of the series, which was directed at open operative procedures. The following procedures were specifically excluded, according to criteria developed before the study began:

1. Procedures in which the skin was not incised, such as closed reduction of fractures;
2. Thermal burns and donor sites of split-thickness skin grafts (excluded because of multiplicity of dressings and operations and the probable employment of different operating rooms);
3. Operations confined to the oral cavity and nasopharynx;
4. Proctologic procedures, such as hemorrhoidectomy and excision of perirectal fistula;
5. Excision of toenail or fingernail;
6. Circumcision;
7. Incision and drainage of abscesses confined to the integument;
8. Operations limited to the vagina; and
9. Operations resulting in death in the operating room.

Thus, although the emphasis was on clean wounds, most contaminated wounds were also studied. In the end, it was found that 14,854 patients met the criteria of the study, among the 18,976 operated on in the 16 operating rooms during the 2½ years of the study.

On the basis of the historical considerations outlined in Chapter II, the study was designed to test the effect of radiation with an intensity of 20 to 24 $\mu w/cm.^2$ and a wave length of 2,537Å at the average level of the operating table (42 in. above the floor) and over an area of 4 × 7 ft., including the operating table and the personnel immediately involved. The intensity would be

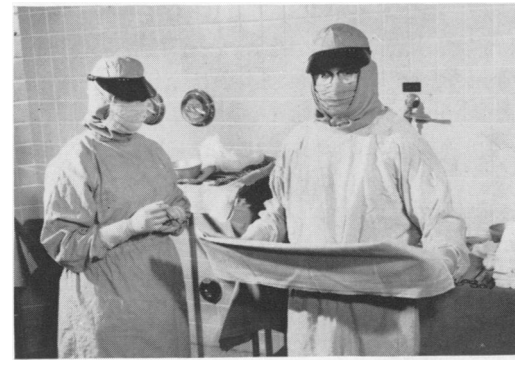

FIG. 1. Demonstrating the hood, glasses, and visor necessary for protection of personnel in the operating room against possible burns of the skin and conjunctiva.

scaled down to a minimum of 10 μw/cm.^{2} at the floor near the walls.

When the desired performance of the ultraviolet installation had been selected, detailed plans of each operating room were forwarded to Westinghouse Electric Corporation for design of the lamp installations. Following the installation of lamps, Westinghouse volunteered to measure the resulting radiation patterns before the study began. Thereafter, monitoring was conducted by the individual institutions at weekly intervals, and the meters were checked every two months for accuracy.

Westinghouse also developed *dummy lamps,* which did not emit ultraviolet radiation, but which, because of their appearance and the light they emitted, hopefully would be indistinguishable from the ultraviolet lamps. Thus, the operating team was not to know with which kind of lamps a given operating room was equipped at a given time.

Both ultraviolet and dummy lamps were to be operated continuously throughout each seven-day period.

Precautions necessary to avoid excessive irradiation of personnel were taken in both irradiated and control rooms. All personnel used hoods, visors, and glasses (Fig. 1–3) in both types of study rooms.

The difficulties of reliable, valid classification of wounds as *infected* or *not infected*

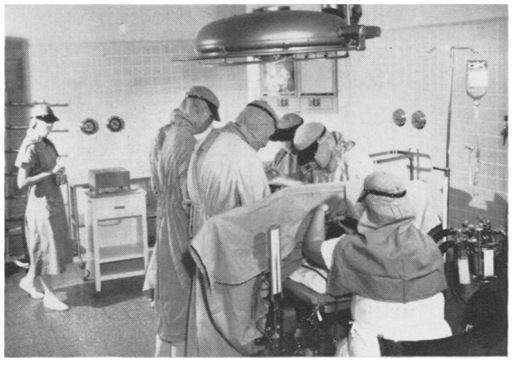

FIG. 2. Protection of the eyes, face, and neck is necessary even for the people who remain in the operating room for shorter periods of time.

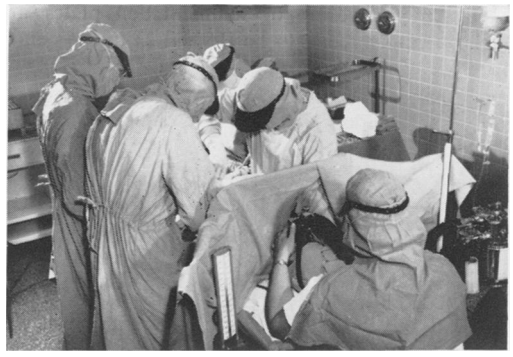

FIG. 3. Protection of the patient's face is obtained by the ether screen and by appropriate drapes. Sometimes a visor is worn by the patient.

occupied the attention of the investigators during the planning stage. It was recognized that classification must be not only unbiased but also as accurate as possible if the trial was to be effective. Before the study began, the investigators met at the Cincinnati General Hospital, September 21–25, 1959, to discuss problems inherent in the study and to examine wounds together in order to agree on terminology and classification. At the same meeting, the epidemiological problems anticipated in studying hospital-acquired wound infections were reviewed under the guidance of Dr. Alexander Langmuir, Chief of the Epidemiology Branch of the Communicable Disease Center, United States Public Health Service. Although the classification finally adopted (relative to the presence of infection) was a clinical one, it was strengthened by the development of uniform criteria relating to the appearance of the wound. To aid the clinical classification, and to provide data potentially useful in understanding the differential incidence of infection, the protocol called for:

1. Cultures at operation of all contaminated wounds and of any tissue or fluid in which infection was suspected;
2. Postoperative cultures of all wounds in which a drain had been inserted;
3. Postoperative cultures to be obtained whenever clinical evidence of wound infection appeared;
4. Weekly cultures of the anterior nares of all personnel in the operating rooms;

5. Daily exposure of sedimentation plates in each operating room, to be studied as to type and number of organisms; and

6. A general infection survey in each hospital during the study.

A *dry run* was conducted in October, 1959. Report forms were completed by the hospital staff and reviewed centrally in order to identify and correct defects in the protocol. The actual study began on November 18, 1959, and was monitored continuously for defects in procedures and reporting. Every two months, the records of each institution were reviewed to ascertain whether random distribution had actually been achieved with respect to sex, age, race, nature of operative procedure, duration of operative procedure, length of preoperative stay in hospital, type of anesthesia, and operating personnel. The forms used for the collection of detailed data are shown in Appendix A. It was agreed that it would probably take about three years to achieve the experience required to answer the basic question concerning the efficacy of irradiation.

Evaluation of Infection

Specific individuals were appointed in each institution to record the circumstances of wound healing, the objective characteristics of each wound, such as drainage, inflammation, primary healing, and infection, being recorded.

As mentioned earlier, the investigators endeavored to establish an objective definition of wound infection that would permit consistent evaluation at all the participating hospitals. On the one hand, bacteriological wound studies alone were considered unreliable; it is not unusual for discharge to be sterile when cultured, even from a wound judged definitely infected, nor is it unusual to recover organisms from wounds that later heal without clinical signs of definite infection. On the other hand, it was believed that classification based only on individual clinical judgment would be too subjective. It was therefore decided that uniform clinical criteria would be used to promote agreement among observers. Wounds were considered *uninfected* if they healed per primam without discharge, and *definitely infected* if there was a purulent discharge, whether or not organisms could be cultured from the purulent material. Wounds that were inflamed without discharge and wounds that drained culture-positive serous fluid were considered *possibly infected.* Stitch abscesses were excluded from definite or possible infections 1) if inflammation and discharge were minimal and confined to points of suture penetration; 2) if the incision healed per primam without drainage; and 3) if healing occurred within 72 hours after removal of sutures. However, in the belief that clinical judgment is most important in the diagnosis of wound infections, wounds were also separately judged infected or uninfected by the examining physician, without being limited to the above criteria. The agreement between the objective designation and clinical judgment was extremely close since the same individual usually made both evaluations. In each instance, the final decision as to whether a wound was infected was made by the designated surgeon(s) involved in the study.

In the great majority of patients, final evaluation was made by the responsible investigator or by the hospital's surgical staff. It was occasionally necessary, however, to resort to telephone calls or correspondence with the patient for a description of wound healing. Losses to follow up accounted for 5.3 per cent of the total number of eligible patients. Patients who lived far from the hospital made 100 per cent follow up difficult at three of the five hospitals.

For further standardization, all wounds were to be evaluated on or about the twenty-eighth postoperative day unless it could be determined at an earlier date that a wound was definitely infected. For pa-

tients who died before the twenty-eighth day, wounds were evaluated at death. Wounds which were re-opened in study operating rooms were classified as to infection at that time and then included in the study as additional wounds.

Drain sites and open wounds were exposed and cultured on the third postoperative day unless infection was suspected earlier, in which case drainage was cultured at first discovery and thereafter at intervals of two days.

Each wound was inspected by a member of the staff at least twice a week and no more than 48 hours before the patient was discharged from the hospital. Each patient was followed by re-examination (or by telephone or letter) for 28 days after operation.

Wound Classification

Clean Wounds. Wounds least likely to be contaminated from endogenous sources were called *clean wounds.* These were nontraumatic, uninfected operative wounds in which neither the bronchi, the gastro-intestinal tract, nor the genito-urinary tract was entered. Cholecystectomies, appendectomies, hysterectomies, and urinary tract operations were also included, if no inflammation was present at the time of operation. Clean wounds were subdivided into *refined-clean* and *other clean.* The former were elective, primarily closed, and undrained wounds, and the latter were not elective, were not primarily closed, or were drained mechanically through the incision or through a separate stab wound. Refined-clean wounds had an over-all * incidence of definite infection of 3.3 per cent, and other clean wounds an incidence of 7.4 per cent.

Clean-Contaminated Wounds. Operative wounds in which the bronchus, gastrointestinal tract, or oral-pharyngeal cavity was entered, but without unusual contamination, were classified as *clean-contaminated wounds.* The over-all incidence of definite infection in clean-contaminated wounds was 10.8 per cent, over three times that in refined-clean wounds.

Contaminated Wounds. Open, fresh traumatic wounds, operations with a major break in sterile technic (e.g., for open cardiac massage), and incisions encountering acute, nonpurulent inflammation were categorized as *contaminated wounds.* The incidence of definite infection in contaminated wounds was 16.3 per cent, almost five times that in refined-clean wounds, clearly indicating that factors other than airborne contamination were responsible for the majority of infections in contaminated wounds.

Dirty Wounds. Old traumatic wounds and those involving abscesses or perforated viscera were classified as *dirty wounds.* This group had the highest rate of infection (28.6%), 8.7 times that in refined-clean wounds. The very definition of the classification suggests that the organisms causing postoperative infection were frequently present in the operative field before operation.

Multiple Wounds. In general, if two or more incisions were made during an operation, each incision was followed separately. This was not done for stab wounds or for cases requiring numerous small incisions that would be difficult and impractical to follow separately, such as vascular operations requiring multiple incisions for venous stripping or thrombo-endarterectomy, tendon repair, cosmetic plastic operations, multiple burr holes, excision of multiple superficial cutaneous lesions, or open reduction of some fractures. The 14,854 patients included in the study contributed 15,613 wounds for evaluation. The 689 patients with multiple incisions represent only 4.6 per cent of the patients and account for 9.3 per cent of the wounds studied.

Physical Factors of Ultraviolet Radiation in the Operating Rooms

Since the early tests by Hart, ultraviolet lamps, transformers, and reflectors have

* I.e., in irradiated and unirradiated wounds combined.

Table 2. Relative Intensities of Wavelengths Emitted by Bactericidal Lamps

Wavelength, Å	Relative energy
1849	nil
1942	nil
2054	nil
2260	nil
2537	100.0
2652	0.14
2753	0.05
2893	0.07
2967	0.37
3022	0.17
3126-3132	1.43
3650-3663	1.30
3906-4077	1.60
4339-4358	3.40
5461	2.25
5770-5791	0.60

been redesigned. In the present study, an attempt was made to design the installations to produce about the same intensity and distribution of bactericidal energy as in Hart's early tests (1942). However, although efforts were made to standardize the factors of irradiation in the separate operating rooms used in this study, minor variations were inevitable because no two operating rooms have identical physical characteristics.

Bactericidal Lamps. The low-pressure mercury lamp in special transmitting glass has been used for the past 25 years for disinfecting air, surfaces, and some liquids. About 60 per cent of the electrical input to the low-pressure arc is converted into the mercury resonance line (wave length 2,537Å). Approximately 90 per cent of the emitted ultraviolet energy from the bactericidal lamps is in this one line (Table 2).

The wave length 2,537Å is very near the peak of the bactericidal action curve, as seen on Figure 4, and the use of that wave length results in a lamp that is very efficient in destroying all types of bacteria, viruses, and fungi.

Two types of low-pressure mercury lamps are manufactured, hot-cathode and cold-cathode. The electrodes in the former are heated to supply the electrons necessary for discharge. The lamps are operated at low voltage and high amperage. Electron emission from the cold-cathode lamp is supplied by a high field, and they require high voltage and low amperage. The 2,537Å line predominates in both types. The application dictates which type should be used. In the operating room, the Westinghouse cold-cathode WL-782-L-30 Sterilamp tube was used because the intensity of the emit-

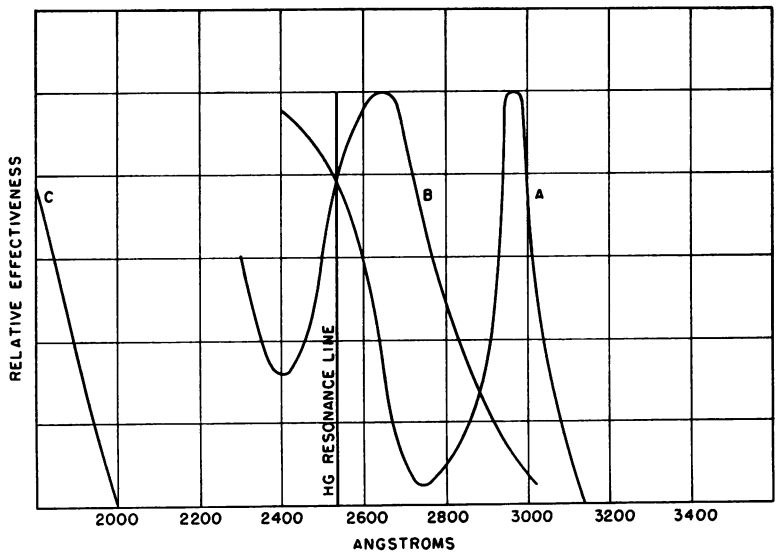

FIG. 4. Relative action spectra for A, erythemal effect, B, bactericidal effect, and C, ozone production.

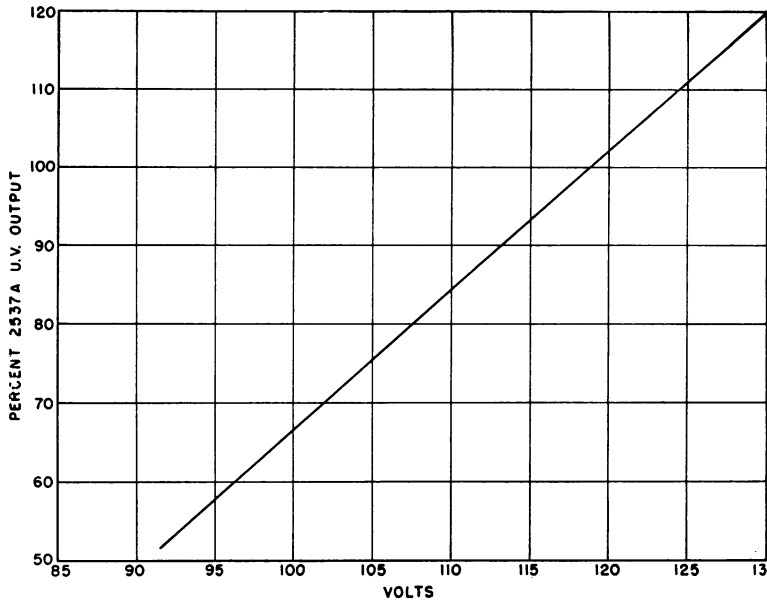

FIG. 5. Effect of line voltage on the relative ultraviolet output of the cold-cathode Sterilamp tube.

ted bactericidal energy could readily be varied by a simple voltage controller on the input line of the transformer (Fig. 5). Such a lamp generates no ozone. The maintenance of bactericidal output from this lamp, which is greatly influenced by the composition of the glass envelope, is nearly constant for a long period after the first 100 hours of burning.

All bactericidal lamps are temperature-dependent (Fig. 6). At low temperatures, the vapor pressure of mercury is very low and consequently the output of 2,537Å radiation is diminished. This can occur, for example, if the lamp is placed in the direct air blast from an exhaust duct of an air-conditioning unit. If the lamps cannot be relocated, they may be protected by shields.

Installation of Ultraviolet Lamps. For more than 25 years, ultraviolet lamps have been used in operating rooms in various ways. In his original tests, Hart (1936–37) suspended cold-cathode lamps from the ceiling to irradiate the air and the entire room directly. He found (1942) that by raising the lamps and keeping the intensity

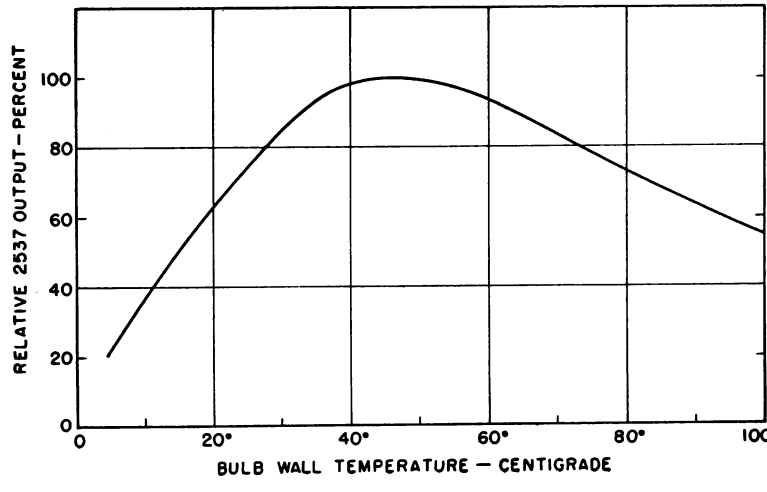

FIG. 6. Relative output of 2,537Å radiation from low-pressure mercury lamp.

Table 3. Intensity of 2537Å Radiation From WL-782-L-30 Sterilamp Tube in SB-30 Fixture at Different Distances, $\mu w/cm^2$

Distance, ft	Fixture				
	1	2	3	4	5
6	13.1	12.8	12.5	11.3	9.6
7	9.8	9.8	9.7	9.0	8.2
8	7.9	7.9	7.8	7.7	6.9
9	6.5	6.5	6.3	6.2	5.8
10	5.1	5.2	5.1	5.1	4.9
11	4.3	4.3	4.4	4.4	4.2
12	3.7	3.8	3.8	3.8	3.9
13	3.2	3.2	3.3	3.2	3.2

of radiation at the operative site constant, at about 20 $\mu w/cm.^2$, he could introduce a greater intensity of radiation into the upper portion of the room while decreasing the intensity on the operating team. The original cold-cathode lamps emitted radiation of low intensity and were difficult to maintain, so that many lamps were necessary to obtain the desired intensity.

Indirect radiation has been used in many operating rooms. High-intensity lamps enclosed in special fixtures are placed on the walls about seven feet from the floor; thus, only the air in the upper portion of the room is exposed to the radiation. Wells showed (1955) that many of the organisms in the air enter the high-intensity zone near the ceiling (i.e., the space 7 ft. from the floor and higher) and are destroyed. In many modern hospitals the ceilings are very low, so that only a small portion of the air would be exposed and the efficiency of this method in killing airborne organisms would be low.

Very-high-intensity bactericidal lamps are sometimes used in air ducts supplying air for operating rooms. Over 99 per cent of the airborne organisms entering the air duct can be destroyed (Nagy, Mouromseff, and Rixton, 1954). However, the air entering the operating rooms of most hospitals is taken from the outdoors, and is generally free of pathogenic organisms (Gaulin, 1957). Pathogenic organisms liberated by the operating team would not be destroyed by such lamps unless the air were recirculated.

Recently, Hart and Nicks (1961) reported the use of reflected ultraviolet radiation in the operating room. Ultraviolet lamps in aluminum reflectors were hung from the ceiling seven feet above the floor and all the radiation was directed onto the ceiling, which was painted with aluminum paint. In this way, radiation of a very high intensity is obtained in the upper portion of the room. About 60 per cent of the radiation was reflected from the ceiling, giving an even distribution of bactericidal energy throughout the entire room. The amount of energy four feet above the floor was 24 to 30 $\mu w/cm.^2$ However, the intensity six feet above the floor was 27 per cent less than if ceiling-mounted units had been used to produce the same intensity at the operative site. The intensity on the floor was 33 per cent higher than that with direct radiation. Reflected radiation would be most useful in operating rooms with low ceilings, in that it would greatly reduce the intensity on the operating team and increase the intensity on the floor. Hart and Nicks have further increased the intensity of radiation in the periphery of the room by mounting as many as 12 shielded lamps on the walls. By using reflected radiation from the ceiling and wall-shielded lamps, a very high intensity is maintained around the operating team without increasing the ultraviolet energy incident on the team or the patient.

Before lamps were installed in operating rooms for this study, the SB-30 fixture with lamps was placed on a goniometer and the intensity of 2,537Å radiation was measured at different distances and angles. Corrected results of these measurements are shown in Table 3.

In the present test, SB-30 fixtures with WL-782-L-30 Sterilamp tubes were mounted on an operating-room ceiling in such a manner as to irradiate most of the room and have an intensity of 20 $\mu w/cm.^2$ of 2,537Å radiation on the operating table.

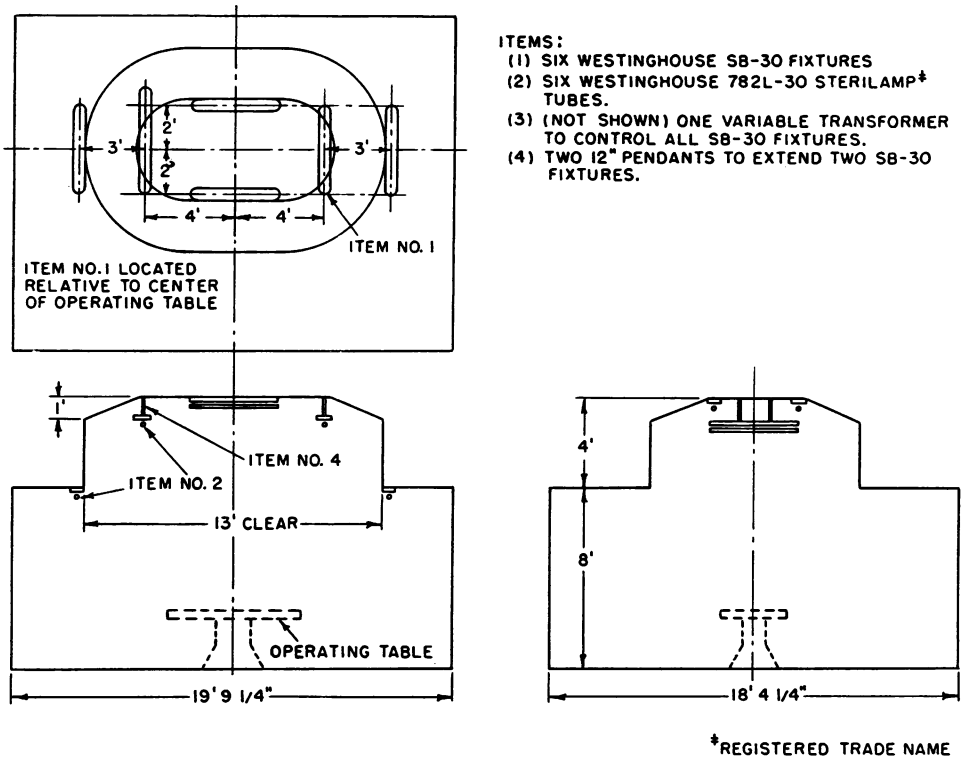

FIG. 7. Typical ultraviolet installation in an operating room with an observation balcony.

On the basis of Hart's work (1942), ceiling mounting should have increased the radiation in the upper portion of the room and decreased the intensity on the operating team. The SB-30 fixtures were chosen because their aluminum backing reflects about 70 per cent of the radiation that would be absorbed by the ceiling if no reflector were used. This, of course, would increase the amount of radiation from a lamp in the room. The intensity of 2,537Å radiation at six feet was found to be 14 per cent higher than from a bare lamp.

Knowing the height, width, and length of the room, one can calculate from the table the approximate intensity of radiation in any portion of the room. Figures 7–9 show typical installations from which the approximate intensity and distribution of bactericidal energy were calculated. Assuming that the input voltage on the transformer to the lamp was 118 v, that air conditioning did not decrease the temperature of the bulb (so as not to reduce the ultraviolet output), and that there were no obstructions, the intensity of 2,537Å radiation on the operating table would be approximately 35 μw/cm.^{2} To control the input voltage on the transformer operating the lamp, a voltage controller was installed outside the operating room.

Measurement of Radiation. The intensity of 2,537Å radiation at the operative site was first measured with a Westinghouse SM200 ultraviolet meter and WL775 phototube. The phototube was originally calibrated with a low-pressure-discharge lamp standardized by the National Bureau of Standards. In making the measurement, the overhead lamp (the standard operating-room spotlight) was pushed away from the center of the operating table to expose the photocell on the center of the table to the maximum 2,537Å radiation. In most cases,

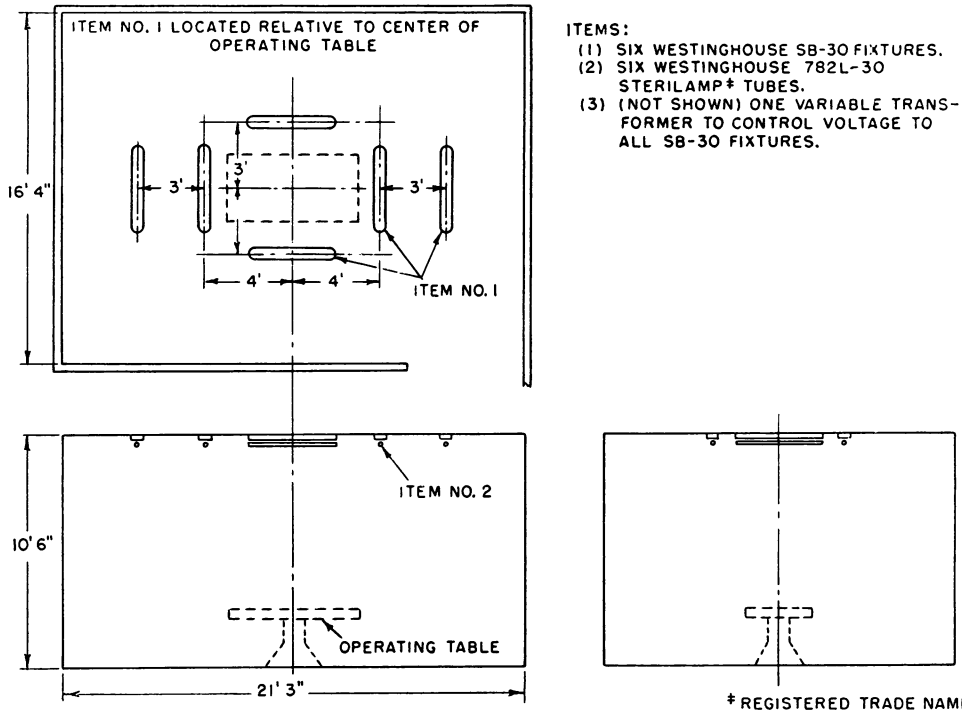

FIG. 8. Typical ultraviolet installation in a small operating room with a low ceiling.

one of the bactericidal lamps was partially shielded. The voltage regulator outside the operating room was adjusted to obtain an intensity of 20 to 24 μw/cm.^{2}

The SM200 meter is a laboratory instrument and an SM600 ultraviolet meter was originally used to facilitate periodic measurement of the lamps. The SM600 meter is designed to measure the intensity of 2,537Å radiation at the surface of the lamp. If the lamps are thus checked with the SM600 meter at the time of calibration, a factor will be obtained that will be applicable for the particular room. If necessary because of depreciation in ultraviolet output, change in line voltage, or change in lamp temperature, the voltage regulator would be adjusted to correspond to the factor.

The SM600 ultraviolet meter, a delicate modified light meter, proved insufficiently rugged for inexperienced hands. The use of the meter was also inconvenient, in that a stepladder had to be used for the measurement of each lamp. For more accurate measurements of radiation intensity, a direct-reading, battery-operated meter with a cadmium phototube was assembled. The phototube was mounted in such a manner that it would intercept most of the radiation from the bactericidal lamps on the ceiling. The meter was calibrated by the National Bureau of Standards in μw/cm.^{2} of 2,537Å radiation and all the installations were remeasured. The average intensity at the operative site was found to have been only 15.5 μw/cm.^{2} with a range of from 12 to 22 μw/cm.^{2} Increasing the input voltage on the regulator would have increased the intensity to 20 μw/cm.^{2} or higher at the operative site, but the meter indicated that the intensity at the periphery of most of the rooms would still be less than the protocol requirement of 10 μw/cm.^{2} Additional lamps were therefore installed in 11 of the 16 operating rooms. The intensity at the operative site in the remodeled rooms was set at 20 to 24 μw/cm.^{2} with at least 10 μw/cm.^{2} at the periphery. The intensity in

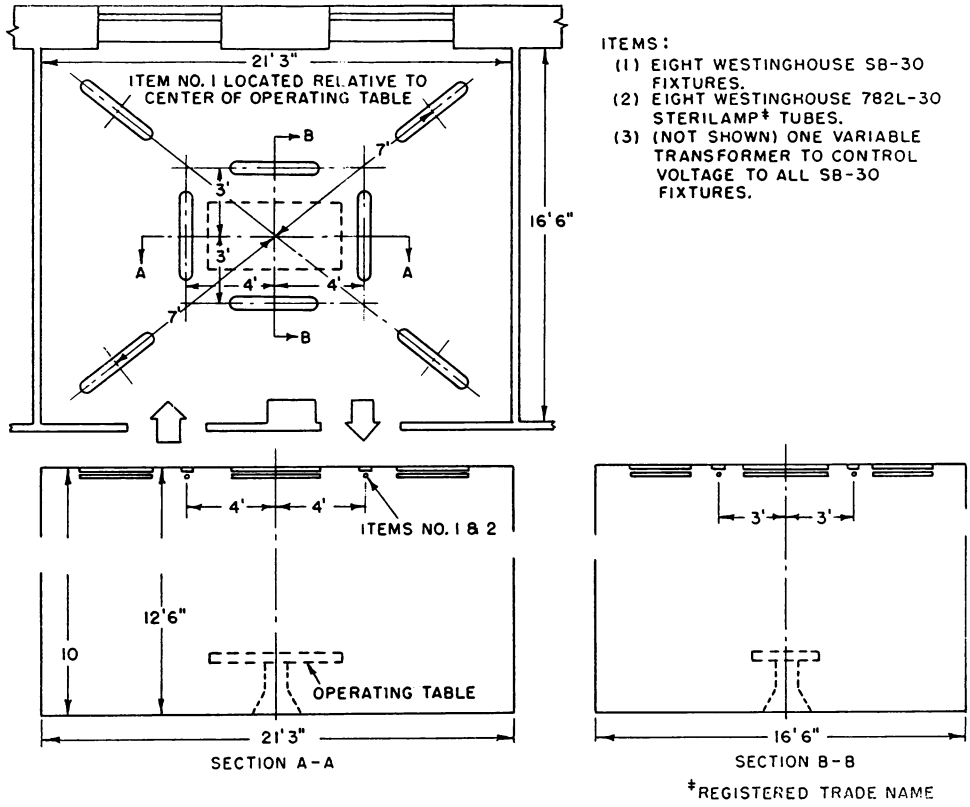

FIG. 9. Typical ultraviolet installation in a large operating room with a moderately high ceiling.

the five remaining rooms was increased to give more than 10 μw/cm.^{2} at the periphery, which gave an average of 26 μw/cm.^{2} at the operative site with a range of 23 to 29.5 μw/cm.^{2} Each hospital obtained a battery-operated meter calibrated by the National Bureau of Standards. The meters were periodically rechecked with a standardized meter.

Because of the initial error in calibration, the first series of tests was labeled *low intensity* and the rest *high intensity*. It should be pointed out that the measurement of ultraviolet radiation is more difficult than the measurement of light. For example, a few parts per hundred million of ozone or mercury vapor in the laboratory air will absorb 2,537Å radiation and result in erroneous phototube readings. A slight change of temperature (Fig. 6) or solarization of the bulb, resulting in blackening of the glass wall of the standard lamps, will also cause errors. The practice in all laboratories is to use a standard lamp for calibrating other lamps of the same type. Variations in absolute units between investigators, and even between readings by the same investigator, can be expected in calibration when such standard lamps are employed.

The bactericidal energy required to destroy various organisms has been determined by many investigators (Table 4). It has been suggested by Sharp (1938) that the amount of radiant energy necessary to kill organisms on seeded plates should be a measure of the effectiveness of the radiation in the operating room. He found, for example, that 2,620 μw-sec/cm.^{2} were necessary to destroy all airborne *Staph. aureus*. If the intensity of radiation at the operating site were 20 μw/cm.^{2}, it would

Table 4. Incident Energies at 2537Å Radiation Necessary to Inhibit Colony Formation in 90 Percent of the Organisms and For Complete Destruction*

Organism		Energy, μw-sec/cm² 90 percent	100 percent
Bacillus anthracis		4,520	8,700
S. enteritidis		4,000	7,600
B. megatherium sp. (veg.)		1,300	2,500
B. megatherium sp. (spores)		2,730	5,200
B. paratyphosus		3,200	6,100
B. subtilis		5,800	11,000
B. subtilis (spores)		11,600	22,000
Corynebacterium diptheriae		3,370	6,500
Eberthella typosa		2,140	4,100
Escherichia coli		3,000	6,600
Micrococcus candidus		6,050	12,300
Micrococcus sphaeroides		10,000	15,400
Neisseria catarrhalis		4,400	8,500
Phytomonas tumefaciens		4,400	8,500
Proteus vulgaris		3,000	6,600
Pseudomonas aeruginosa		5,500	10,500
Pseudomonas fluorescens		3,500	6,600
S. typhimurium		8,000	15,200
Sarcina lutea		19,700	26,400
Serratia marcescens		2,420	6,160
Dysentery bacilli		2,200	4,200
Shigella paradysenteriae		1,680	3,400
Spirillum rubrum		4,400	6,160
Staphylococcus albus		1,840	5,720
Staphylococcus aureus		2,600	6,600
Streptococcus hemolyticus		2,160	5,500
Streptococcus lactis		6,150	8,800
Streptococcus viridans		2,000	3,800
Yeast			
Saccharomyces ellipsoideus		6,000	13,200
Saccharomyces sp.		8,000	17,600
Saccharomyces cerevisiae		6,000	13,200
Brewers' yeast		3,300	6,600
Bakers' yeast		3,900	8,800
Common yeast cake		6,000	13,200
Penicillium roqueforti	Green	13,000	26,400
Penicillium expansum	Olive	13,000	22,000
Penicillium digitatum	Olive	44,000	88,000
Aspergillus glaucus	Bluish green	44,000	88,000
Aspergillus flavus	Yellowish green	60,000	99,000
Aspergillus niger	Black	132,000	330,000
Rhisopus nigricans	Black	111,000	220,000
Mucor racemosus A	White gray	17,000	35,200
Mucor racemosus B	White gray	17,000	35,200
Oospora lactis	White	5,000	11,000

*Compiled from various sources, such as Hollaender (1942), Rentschler et al. (1941), Nagy (1948), and Sharp (1939).

take 131 seconds to destroy this organism. Kraissl and associates (1940), using a different method of exposing organisms, found that all the organisms on their plates were destroyed at the operative site in less than five minutes. Hart, Devine, and Martin (1939) showed that over 95 per cent of *Staph. albus* seeded on plates were destroyed in 60 seconds. This would indicate an intensity slightly higher than 20 μw/cm.² at the operative site. The age of culture, the strain of organism, and especially the method of seeding the plate influence the amount of energy necessary to destroy the organisms. Therefore, this method of measuring radiation could not be used except with a standard technic and organism.

The criterion used by Hart and Nicks (1961) to determine the efficacy of an ultraviolet installation has been to count the number of organisms settling on sterile culture plates during an operation. Their composite studies indicate that, with the operating room in use, the plates averaged approximately 23 colonies/hr. of exposure without ultraviolet radiation and 8 colonies/hr. (on shielded plate) with ultraviolet radiation. The radiation intensity in Hart's operating rooms was 20 to 24 μw/cm.² However, operating rooms whose air was changed at different rates would need radiation of different intensities. For example, Wolf and associates (1961) have shown that many organisms can enter an operating room from the corridors, especially if there are only six room-air changes per hour. Their study showed that in one particular room, 358 ft.³/min. of air contaminated with an average of 15.5 organisms/ft.³ entered the upper portion of the room through the doorway. Such a room would probably require radiation of a much greater intensity to destroy the additional organisms than would operating rooms that do not have such a backflow of air.

Problems Encountered During the Study

Among the obvious problems was the possibility that any unshielded part of the face, neck, or shoulder of the operating personnel might be burned by long exposure. Prevention of conjunctivitis was the most serious problem.

Bactericidal radiation can produce erythema (Fig. 4). Nearly twice the amount of 2,537Å radiation is necessary to evoke erythema of normal skin as of 2,967Å radiation (most active in the *suntan* region). However, the results are not the same. Even large doses of 2,537Å radiation will not produce blistering or tanning of the skin; nearly all of it is absorbed by the corneum with only a small amount penetrating to the Malpighian layer. Rusch and associates (1941) stated that no skin tumors can be produced by 2,537Å radiation, no matter how large the dose.

The protective clothing for the operating team is shown in Figures 1–3. Long-sleeved gowns protect the arms and a small cape sewed to the cap protects the back of the

neck and the side of the face. Ordinary gowns absorb about 99 per cent of the impinging radiation. The eyes must be protected by an eyeshade and, if an individual is working in the room for any extended period, he must wear glasses because many materials and metals reflect 2,537Å radiation (any type of glass or plastic lens is adequate). The patient's eyes are closed and covered during the operation.

The amount of energy of 2,537Å wave length necessary to produce a threshold keratitis is only about one-tenth that necessary to produce a minimal perceptible erythema (Rooks, 1945). All the radiation is absorbed by the cornea and conjunctiva, and therefore none penetrates to the lens. No permanent eye damage from this type of radiation has been reported. Hudnell and Chick used 100 to 400 times the threshold dose of 2,537Å radiation in treating corneal infections successfully and reported no permanent damage to the cornea or other portions of the eye (1962).

Some operating-room personnel were moderately distressed by having to wear the protective cap, visor, and glasses. It was difficult for persons not accustomed to glasses to wear them, and many complained of the fogging of the lenses. It was frequently complained that dust gathered on the visors during an operation and then occasionally fell into the wound from the visor, but in most cases the same dust would have entered the wound directly instead of first collecting on the visors. It is, however, undoubtedly true that the protective clothing is somewhat cumbersome, especially in non-air-conditioned areas.

Most of the irradiation reactions actually reported were due to failure to comply strictly with established rules. By failing to wear the protective glasses, several people developed severe, but transient, conjunctivitis. Others developed painful erythemas in areas that had not been completely covered.

Little difficulty was encountered with the patients. Care was taken, however, to shield their eyes and faces throughout the procedures. Often the skin was exposed around a wound for varying periods of time but that did not create many problems. Two groups of patients seemed to develop cutaneous burns with unusual ease: newborn infants and patients with Cushing's syndrome; in both groups the cutaneous changes regressed rapidly. There were several false alarms in which it was believed that the peritoneal surface of the intestines had been burned during a long procedure. In most of these, it was found that the bowel had been allowed to dry; this occurred seriously at least once in a room equipped with dummy lamps. Several patients also developed conjunctivitis before the rigid adherence to the technic for protection of the patients' eyes.

The double-blind nature of the study was far from perfect, because some materials used in the operating rooms were observed to fluoresce under the ultraviolet lamps; certain detergents apparently left a fluorescent residue on the clothes of some of the operating-room personnel. However, although operating-room personnel often learned which lamps were being used in their room during an operation, it seems unlikely that such information influenced the subsequent evaluation.

Another problem was the accuracy of the meter used as a standard for measuring ultraviolet intensity (discussed above). Regardless of the design of the ultraviolet fixtures, the movement of the overhead and accessory spotlights (standard operating-room lights) could, at any given moment, minimize the ultraviolet irradiation of the wound by unintentional shielding. No complete solution to this problem is known.

The output of ozone by the ultraviolet lamps, deemed to be a possible nuisance before the study began, actually was never recognized as a problem during the study.