RESEARCH PRIORITIES AND TREATMENT TRIALS IN PAPER CONSERVATION

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The AIC Task Force on Conservation Science is in the process of developing a list of research priorities in conservation, as assessed by the practicing conservator. This list will be an update and extension of the 1979 and 1984 lists compiled by two national committees (National Conservation Advisory Council 1979; NIC Scientific Research Priorities Committee 1984). It also complements similar work being undertaken by the Conservation Science group in the AICCM (Australia) and the Conservation Research Policy Group of the Conservation Unit of the Museums and Galleries Commission in the UK (Conservation Unit 1989).

Our list is not intended to be a document that dictates to scientists what research they should be doing. Instead, it is intended to be serve as a communication tool, to help conservators define and explain to scientists where the most important and pressing problems lie in practical conservation work. In order to reach as many practicing conservators as possible, input is being solicited from the AIC membership through the specialty/sub groups (Architecture, Book and Paper, Conservators in Private Practice, Objects, Paintings, Photographic Materials, Textiles, and Wooden Artifacts). Because of the strong interest of the Book and Paper group, we chose to begin there, and a short questionnaire was sent to each member in the fall of 1990. About 100 detailed responses have been received.

The purpose of this survey is to identify and prioritize unsolved problems in conservation treatment. A prioritized list of problems may be useful for focusing scientific research and for fundraising. It is not intended to discourage research in areas not listed. The survey should not be seen as the final word on the subject, but as one information source. When completed, the compiled results for all specialties will be made available to the AIC membership.

In this paper we first summarize and briefly discuss the results of the questionnaire on research priorities in paper conservation. Secondly, we describe the treatment trial format, as developed in medical research, and propose it as one possible mechanism for collaboration between conservators, scientists, and statisticians that might work well for solving some of the problems noted as high priorities by respondents to the questionnaire.

RESEARCH PRIORITIES

We asked respondents to address the question, "What areas should be a focus for research efforts?" Judging from the number of times specific areas were mentioned, the greatest concerns are:

1. The effects of aging on spot treatments. Very often spot treatments can be detected with ultra-violet light. Will these treatments become visually detectable with time?

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2. The effects of water or organic solvents on paper, both immediately and in the long term. Greater detailed knowledge is needed about both the chemical and physical effects. Also of great concern is to determine the effects of the duration of contact (e.g., paper submerged for one hour versus paper submerged for four hours).

Other problems frequently mentioned include bleaching (light), selection of adhesives, deacidification, causes and treatment of foxing, and consolidation of paper or foxing of pigments/inks/colorants during a washing procedure.

We also asked the question, "What general observations or comment would you like to make about the correlation between scientific research and your actual conservation practice?"

The greatest number of respondents indicated problems with relevance of research results to their practice, and little correlation of scientific studies with what they see happening in their practice. Mentioned most often is the fact that so much laboratory research is done only with Whatman Filter paper, yet conservators never use that paper.

The next greatest number of respondents would like to see more joint studies and interaction with scientists and greater communication and joint publication. Some respondents report that the correlation between research and practice is good.

SURVEY CONCLUSIONS

In summary, it appears that most conservators realize that much good research has been done and is currently underway, but that the greatest problem at the moment is the question of relevance of laboratory research to actual conservation practice and the need to increase awareness on the part of laboratory scientists regarding conservation treatment procedures and problems. A number of conservators perceive that the field as a whole seems to be moving away somewhat from the need for more analysis of materials towards a need for analysis of treatment problems.

INCREASING CONSERVATOR INPUT IN RESEARCH: THE MEDICAL MODEL OF TREATMENT TRIALS

As an outgrowth of the questionnaire response, we investigated the medical model of the treatment trial as a potentially useful addition to conservation research methods. Medical and conservation research share the problem that the usefulness of laboratory experimentation is limited. Eventually, treatments must be carefully tested in the context of a real practice -- human patients for doctors, and works of art for conservators. This will almost always mean the introduction of additional uncontrollable variables. Yet the results of careful experimentation with real subjects are usually more applicable to treatment practices in general than are the results of less realistic laboratory tests alone.

The physician (or conservator in our case) must be a principal investigator rather than or in addition to the scientist, since she/he has the experience to know which treatments should be tested, is the only one who can actually apply the treatments to real works of art, and who has the final responsibility for the works. The medical profession has devoted great effort over decades to develop and refine optimal treatment trial procedures, and we should be able to benefit from their experience. Procedures they have made standard to treatment trials are briefly described here, along with some potential obstacles to the adoption of treatment trials in conservation research. The

rationale and procedures for treatment trials in conservation are also discussed in detail in a recent publication on principles of experimental design in conservation research (Reedy and Reedy 1991: 91-99).

Medicine and Conservation

The medical profession and the conservation profession share the ethical concern that arises if one must apply treatments that have not been adequately tested and evaluated for three important properties:

1. Do they really work as they are intended to?

2. Does the treatment itself actually cause harm soon after application, or after the passage of time?

3. Is the treatment selected definitely the better treatment to choose compared to other potential treatments?

The AIC Code of Ethics does not specifically include guidelines concerning any of these ethical dilemmas. The closest it comes to providing guidance is to say that, "the conservator should honestly and sincerely advise what he considers the proper course of treatment" (AIC 1990: 23). But there are no explicit standards in the field regarding how one can or should demonstrate what is a proper course of treatment or evaluate multiple treatment choices.

Due to the relative newness of the conservation profession, many treatment tests found in the literature or passed along through conferences or by word of mouth are of a very preliminary nature. Many are subjective, haphazard tests on one or a few objects that are probably not widely generalizable. The Code of Ethics does not state that ubiquitous conservation treatments should undergo rigorous, objective, or even adequate testing. So in a sense, as a profession we have given ourselves permission to apply potentially harmful or ineffective, untested treatments as long as one is "sincere" in advising what one thinks to be a proper course of treatment. Occasionally, inadequate testing of treatments prior to use on important artifacts has, after moderate aging, proven to be disastrous (Bock and Bock 1991).

The author of a recent book on treatment trials in medicine, Clifford Meinert (1986: 15), notes that the history of medicine is filled with drugs, devices, and other treatments originally heralded as great advances but later shown through treatment trials to be useless or even harmful. These mistakes include modern drugs -- of the 3,185 prescription drugs reviewed by the FDA prior to 1982, 31% were classified as ineffective.

For this reason, the medical profession has devoted much effort to developing and refining the concept of the treatment trial (also called the clinical trial). The treatment trial is widely considered to be the basis of modern medicine. The development of this research method is cited as the reason for most major medical advances that have occurred this century (Meinert 1986: 3-10). Today the FDA will not consider approving any drug for use until it has been documented to be effective and safe in two separate clinical trials.

Because of the similarities between medical practice and conservation, and the great contribution of treatment trials to advances in medicine, we propose that the treatment trial format

should also be considered for use in conservation. We therefore define and briefly describe that format as it is used in medicine.

Treatment Trials

In medicine, a clinical trial is a planned experiment designed to test the efficacy of a treatment by comparing the outcomes in a group of patients given the test treatment with the outcomes observed in a comparable group of patients receiving a control treatment. Both groups are enrolled, treated, and followed over the same time period. The control group may receive a placebo (e.g., no treatment) or a standard treatment that is the logical alternative to the new treatment.

The term trial means to choose, sort, select, or try. Here the choosing refers to the careful comparison of a proposed new treatment to either a standard treatment or to no treatment at all, in order to objectively determine which procedure is the more successful. There are several critical components of the treatment trial format:

1. The trial must include enough patients (or art objects) to do a statistical analysis to adequately evaluate the results. Most clinical trials compare two treatments and average about 25 patients in each group (Meinert 1986: 10). Clinical trial investigators work with statisticians to design their experiment, then again to statistically analyze the results. It is extremely important to clearly define the class of objects eligible for the study so that other researchers can assess whether or not the results apply to their objects. If eligibility is restricted too much, for example, from "photographs with mold" to "albumen prints produced in a given 20-year period, with a particular species of mold," it will get more difficult to obtain enough objects within a reasonable period of time.

2. The principal investigator in medical treatment trials is always a physician (who as the "treater" is analogous to a conservator). Other trial investigators may or may not include scientists (such as biochemists) along with statisticians. The physician is the one who has the expertise to know which treatments should be tested, who can directly apply treatments to patients, and who can best evaluate how well a treatment worked (in conjunction with statistical results).

   This format differs from theoretical, preliminary, or basic scientific studies done by scientists in the laboratory. The physician is better trained and more experienced at assessing the effects of treatments on real human patients, and could not ethically (or legally) permit a scientist to diagnose or treat a patient. The physician takes full responsibility for determining if a patient should be removed from the trial early due to adverse effects of the treatment, and makes the final decision about how to proceed in his or her medical practice based upon the results of the trial.

   We propose that similar treatment trials in conservation, with conservators as principal investigators, could be a useful adjunct to scientist-led laboratory studies. In trials with real works of art, treatments must be performed by conservators. Conservators have the training and experience to propose potential treatments for testing (Hedley 1990: 8) and to contribute, in conjunction with the input of scientists and statisticians, towards evaluating results.

3. A number of standard scientific principles of experimentation must be included in the trial procedures to ensure that the results are reproducible and reliable. The most important of these are:

(a) Randomization of subjects (or objects) to treatment groups prevents bias from entering into the selection process. The surface reason for randomization is that all statistical hypothesis tests assume in their mathematical probability calculations that randomization was done. If that assumption is violated, statistical results are not valid. A deeper underlying reason is that it serves to distribute between treatment groups, in a manner with known probabilities, the uncontrolled differences in objects. This is especially important for real art objects. For example, in the study of photographs with mold, we rarely know all details of the history of each object. If too many objects that happened to have one history, such as being displayed in a smoke-filled room, were all put into one group, apparent treatment differences might actually be due to past smoke exposure differences. Randomly distributing the exposed versus unexposed between treatment groups will mitigate that problem. There are numerous established procedures for carrying out randomization so that the results will have known statistical probabilities (Reedy and Reedy 1991: 51-56).

(b) Blinding prevents any subjective biases from affecting the results. This means that the person evaluating how well a treatment worked should not know which subject (or object) received which treatment.

(c) Controls or comparative treatments are used, since random effects can occur that might otherwise cause one to erroneously conclude that an ineffective treatment was effective.

(d) Treatment protocols are clearly written down to ensure that all participants in the trial are following the same procedures, and so that other investigators can reproduce the experiment.

(e) Outcome measures can be continuous variables such as an instrumental reading (e.g., blood pressure change; color change) or binary (e.g., dead or alive; has cancer or not; is visibly corroded or not). Whether the variables are continuous or binary or include some of both, anyone collecting data or measuring outcomes for the trial must pass a certification process to demonstrate that they are recording the data correctly. Certification is often required for treatment application as well, to assure standardization at every step, and thus comparability and reproducibility.

(f) Sample size must be adequate to give confidence in results. Medical trial investigators consult with a statistician on this point, since the adequate sample size varies depending upon the number of treatment groups and the number and type of outcome measures.

The most successful treatment trials are those that are part of a research program involving a series of trials that build an accumulation of knowledge, and which gradually refine trial eligibility rules. Trials are not a substitute for laboratory research with surrogate objects. In medical research, no treatments are included in a trial until it has been shown through preliminary laboratory testing that they are likely to work and that they are probably safe.

Treatment trials following the above format have been used regularly in evaluating medical treatments since the 1930's. There is even a Society for Clinical Trials and a specialized journal, *Controlled Clinical Trials*. Every necessary step in planning, implementing, and evaluating a treatment trial has been written down and discussed in great detail in the medical and statistical literature (Armitage 1975; Food and Drug Administration 1981; Levine 1981; Friedman, Furberg, and DeMets 1982; Tygstrup, Lachin, and Juhl 1982; Bulpitt 1983; Pocock 1983; Shapiro and Louis 1983; Buyse, Staquet, and Sylvester 1984; Elashoff and Reedy 1984; Fleiss 1986; Meinert 1986).

There is a distinction between single center and multicenter trials. The single center trial is carried out in one clinic location, and typically includes two treatment groups with 25 patients per group. This type of trial usually requires 1-3 years to complete. Multicenter trials are sometimes necessary in order to obtain a large enough sample size, since one clinic location may not be able to fill a 25 patient group on its own. An additional advantage of multicenter studies is that the results are more generalizable and reproducible, since the subjects are less homogeneous. However, a disadvantage is that multicenter studies are more difficult to coordinate.

Funding of Treatment Trials

An important difference between treatment trials in medicine and in conservation arises in the question of who will fund such a project. There are two primary sources of funding for clinical trials in medical research: NIH (the National Institutes of Health), and drug companies.

Conservation does not have a federal grant program similar to that provided by the NIH. We need to develop more resources in that area. For example, art conservation research does not clearly fit under any program of the National Science Foundation, but perhaps we should begin lobbying strongly for inclusion. In addition, we could try to develop funding for treatment trials under the nonfederal programs that have traditionally funded conservation. We could make more efforts to secure funding from companies supplying conservation materials. However, here we are at a disadvantage compared to physicians. If a drug is found to be effective as a treatment, the market for that drug is often quite extensive. The monetary advantages of identifying a successful conservation treatment tend to be much less attractive.

Good planning in a treatment trial can significantly decrease required costs. Examples well-documented from the medical experience include: avoid changing forms and procedures midway through a trial (you can always do the follow-up trial a different way); avoid undisciplined data collecting (e.g., "while we're at it, why don't we record everything we can think of to say about each object since maybe someday we'll want to ask some additional questions about the data"); don't have too many secondary projects going on (e.g., during a trial of cancer cures one of the investigators is also interested in studying the relationship between smoking and baldness with the same set of patients, another between coffee drinking and high blood pressure, etc.); and don't worry too much about having sophisticated technology. If the research questions can be answered through simple observations and measuring techniques, don't worry that a lack of expensive instrumentation might make the study look "unscientific." What is important is the proper design of the study, the appropriateness of treatment protocols and outcome measures, a professional level of statistical treatment, and the clarity of the communication of methods and results.

We predict that experimental treatment trials with real works of art, in a realistic clinical setting with conservators as principal investigators, should lead to advances in conservation as they have in medicine. However, there are some obstacles that must be overcome before such trials can be successfully implemented.

1. Contrary to the accepted role of the physician/investigator in medical research, many members of our field have the idea that only scientists can or should be directing the testing of conservation materials and treatments (Anony. 1988: 16). Conservators need to learn how to be principal and co-principal investigators in practical treatment trials. This includes the important phase of writing up the results for publication.

2. There are almost no precedents in this field for working as a team with statisticians on experimental design and data analysis, unlike the field of medical research (Reedy and Reedy 1988, 1991). One can easily find numerous medical statistics specialists as well as university departments and journals devoted to various aspects of biostatistics; the same situation is not found in conservation research.

3. We need to put effort into developing funding sources. This should not be insurmountable, since a typical conservation treatment trial (two treatment groups of 25 objects each, over a 1-3 year period, including materials and consultants) would probably not exceed $25,000.

Controlled treatment trials, following a well-defined format, have resulted in major advances and breakthroughs for modern medical practice. They have also unmasked many ineffective and harmful treatments. It is reasonable to predict that conservation practice could be similarly improved by incorporating treatment trials into our repertoire of research methods. Many of the research priorities listed by respondents to the Conservation Science Task Force questionnaire could serve as the basis for experimentation with this research methodology.

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