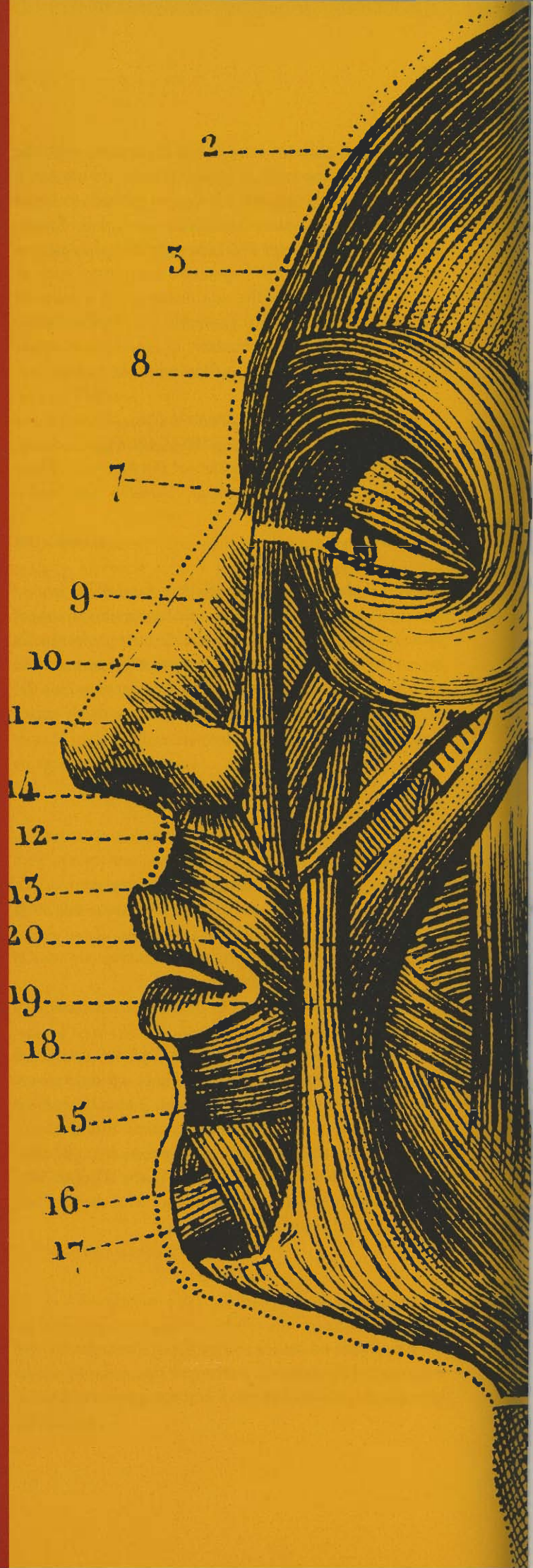


CLINICAL QUALITY IN OUR CHANGING HEALTH CARE

BY TERRY P. CLEMMER, M.D.

The nation's concerns with current health-care problems are primarily focused on access and affordability. The dilemma is how to create a system that gives universal access to every U.S. citizen and controls costs without jeopardizing the quality of health care. There are three approaches to this dilemma:



1. regulation:

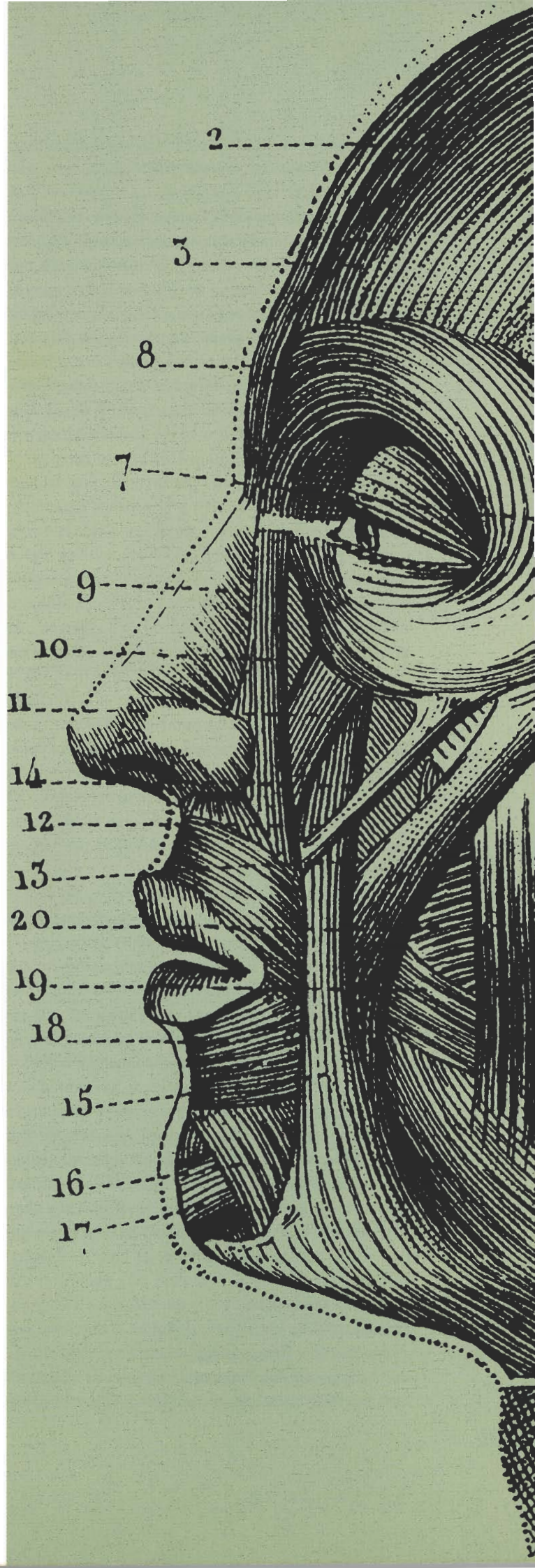
to administratively and/or legislatively mandate access, control reimbursement, and, if necessary, govern the practice of health care

2. competition:

create an environment in which economic forces drive costs down while providers compete for business based on the quality and cost of service

3. focus on quality:

have the health-care providers establish programs to improve the quality of practice in a scientifically defensible and credible way and let improved quality reduce cost and improve access



ACCESS, AFFORDABILITY, AND
QUALITY OF CARE RELATIONSHIPS

In order to understand the best solution to this dilemma, it is important to first understand the relationship of quality to cost. Many people still believe that high quality costs more. That is true of design quality, but not true of production and conformance quality: When making a specific object, the better the engineering and design, the higher the quality of the materials, and the more skilled the craftsman (all of which increase cost)—the higher the quality and the cost of the object. In production, however, focusing on the quality of the manufacturing process is very cost efficient. Making each part to exact specifications, assembling the parts correctly the first time every time, doing it the same way, and disallowing artistic liberty of individual workers produces a precision, high-quality product at lower cost by avoiding defective merchandise. Whenever you create a defective product you have only three options: throw it away, which costs more; fix it, which costs more; or sell it defective, which produces a dissatisfied customer and in the end costs more. There are other costs of poor quality products. Poor quality in the manufacturing process is inefficient and results in low productivity and high employee turnover. In addition there are increased warranty costs of defective products (malpractice), customer replacement costs (marketing), and the ripple effects of a poor reputation. Thus, Edward Deming's basic principle was to focus on the quality of the product and the manufacturing process as the key to lowering costs.

Likening manufacturing to health care is not my intent. The concept that quality is cost effective, however, is an important paradigm that does relate to health care. Once we understand this concept, the methodology to resolve the problems of access and affordability becomes clearer. Legislating universal access to health care will likely increase global cost and may inhibit quality efforts. Controlling costs by regulation or cost competition, which has been our mode over the past few years, has created increasing access problems and in some areas reduced quality. On the other hand, by focusing on improving the quality of health-care delivery, cost will be reduced and access facilitated. If one places access, affordability, and quality on an interrelationship diagram, quality is the element that consistently influences the others in a positive way.

SHIFTING PARADIGMS

First: As most people intuitively realize, the solution to our health-care dilemma cannot be resolved by passing laws, making businesses more competitive, or by restructuring

the insurance industry and reimbursement rules. Tort and antitrust reform will not be the solution. The solution to the problems lies with the health-care providers. Without changing the way medicine is practiced, there is no solution to the quandary of improving quality, reducing costs, and achieving universal access. The physicians, nurses, therapists, and hospital administrators must lead out and take charge in resolving the dilemma we face today. We cannot rely on politicians, bureaucrats, industry, new technology, or outside consultants to find the solution. It will be up to the front line workers. Unfortunately we have not taken this responsibility upon ourselves. As a result of our complacency, others are attempting to find legislative and bureaucratic ways of resolving the problems. The changes they are proposing will be ineffective but may act as a catalyst to move the health-care industry into doing something.

Second: It requires a change in attitudes. Intimate collaboration across health-care disciplines is a must. Willingness to abandon stylistic practices and to standardize care will be required. Relinquishing our infatuation with technology as the solution to health-care problems and focusing more on process is essential. We must commit to keeping the population we serve well, not just treating their illnesses.

Third: Health-care providers must educate themselves about quality methods. Even more so they must establish new methodologies to establish scientific and statistical credibility. Experience gained in industry may be used, but new waters must be charted and new methodology developed to make it fit the health-care industry so it will be implementable, effective, and reliable. They must understand their job is not to just care for patients but also to improve how they practice. This is a cultural change. It will require hard work and education. Some have been able to demonstrate, however, that it is effective in improving quality and reducing costs.

THE NEW PARADIGM

Quality improvement and cost reduction go hand in hand, and the pressure to demonstrate the effectiveness of our efforts in this area is considerable and data dependent. In order to truly evaluate effectiveness, we need to develop new quality paradigms.^{1,2} This also means developing new skills and tools.³ Quality assurance was the old method used to try to improve care. It did not work very well. We know that there is a great variability in practice and in defining quality. Outcomes quality can be measured in many different ways. Examples include cost,

length of stay, complication rate, and mortality. In the graphs below, the bell curves represent variation in quality. We arbitrarily say that when practice is within two standard deviations of the mean, we consider that practice to be acceptable. For example, if the physician's mortality rate is similar to everyone else's, it is acceptable. We also define a group two standard deviations below the mean and label them as poor quality providers or "bad apples." This group has complication or mortality rates that are too high, or under the new health-care paradigm, their hospital care is too costly. All of our quality assurance activities in the past have been geared to finding these outliers (the bad apples) and attempting to get rid of

wasn't that long ago that the correct method of caring for an acute myocardial infarction was at least three weeks of absolute bed rest. If you didn't, you were an outlier. Today that practice would be considered improper care and by today's paradigm we were all poor practitioners.

The second fallacy is that getting rid of outliers (*figure 2*) will have a significant impact on the overall outcome of the population. In reality, it will have very little effect on the mean outcome, and the previous outliers are quickly replaced by new ones. The last fallacy is that you can actually get rid of outliers. Those who have tried understand how difficult it is to eliminate them from the health-care system.

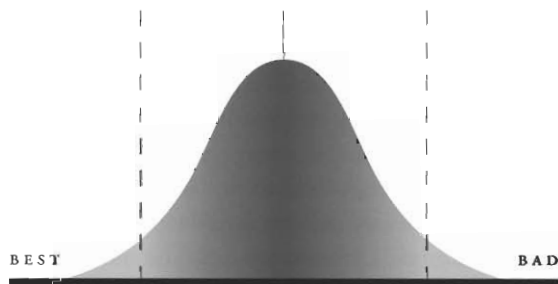


figure 1

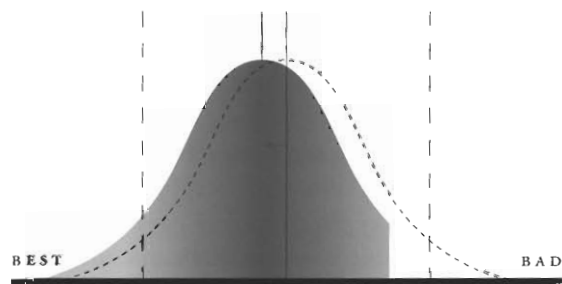


figure 2

QUALITY ASSURANCE

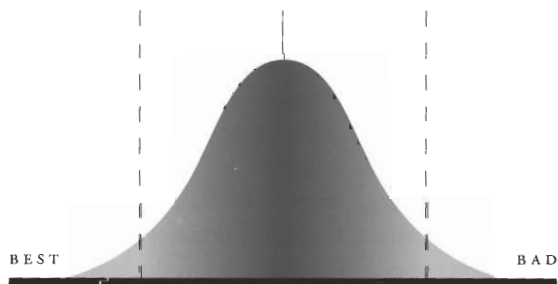


figure 3

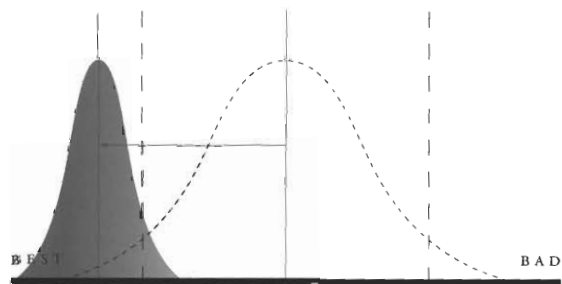


figure 4

CONTINUOUS QUALITY IMPROVEMENT

Under the quality assurance paradigm demonstrated by figures 1 and 2, the goal was to monitor and identify practitioners who were below the currently accepted standard and re-educate or remove them from practice. In reality this improves the system very little. Using the quality improvement paradigm demonstrated by figures 3 and 4, the goal is to define the practice of those with the best outcomes and then standardize the process and teach others to practice that way to include the poor performer. Thus, large improvements in care can be realized within the system.

them. That is the purpose of all the chart reviews that look for high length of stay, cost, and complication rates. The premise is that if we can identify the outliers and eliminate them, poor health care will be abolished, and we will significantly improve outcomes. There are several fallacies to this thinking. First, the theory is based on the idea that outliers are legitimately bad persons who want to provide poor care. That is not true. They have learned to practice like the rest of us. The problem is that our care is so variable no one knows what is correct. We all do it differently and this individual just happens to be the one who ends up more than two standard deviations below the mean in a particular area of practice. As a reminder, it

The quality paradigm is now changing. Our emphasis is now on defining how the practitioners with better outcomes on the other end of the bell curve practice (*figure 3*). What do they do that is right, and how can the rest of us learn to practice like them? How can we make everyone better? To do this we must learn to describe the process of care in great detail and then teach that process to others and shift them over to better practice (*figure 4*). This is called quality improvement. The basis of this principle is to reduce variability and standardize care.⁴ The process of standardizing care is very important and to make the improvement process continuous, the standard must remain dynamic and have a mechanism to

evolve and the capacity to be challenged. These are the concepts Edward Deming introduced to the industrial complex in Japan and taught them to practice.⁵ We are now attempting to introduce them into medical practice, and examples are beginning to emerge demonstrating how care can be improved this way. It should be emphasized, however, that this is a statistically and scientifically sound process that is data dependent and the effects measurable. The computer is invaluable in discovering variability in practice and best used if an integrated clinical data-base is available. In addition, it can be programmed to produce control charts to monitor the quality improvement activities.

STANDARDIZING PRACTICE: THE KEY TO REDUCING VARIABILITY AND IMPROVING QUALITY

There are many advantages to standardizing care. In hospitals where many of a certain patient type are cared for, such as coronary artery bypass surgery patients, outcome improves. Much of this improvement is due to the routine or standardization of care that results from repetition. Mistakes are reduced. An example used in most intensive care units is in mixing intravenous infusion drugs. If mixed differently each time, dosages are more commonly incorrect than if the concentration is always the same. In addition, the care is more uniform if all the care team members use the same principles and decision logic from shift to shift and day to day.^{6,7} And, when everyone uses the same terminology and interprets the data similarly they communicate better.

Standardization can also reduce cost by reducing the inventory of supplies and drugs required by the institution. Routine also reduces waste and personnel time. With standardization, quality-assurance programs are strengthened, since it is easier to identify breeches in the standards. Where standardization is accepted in the institution, changes that improve care are simplified and more readily accepted.

One major problem today is that we have difficulty defining how we care for patients. For example, the process of caring for a ventilator-dependent patient differs, depending on what hospital they are in and who the physician is. Even individual physicians change their style from day to day. For this reason it is very difficult to know if one method of ventilator care is better than another or how to modify the process of care to improve outcome. Care standards help identify where improvement can be made and allow evaluation of the effectiveness of changes in the standard.^{8,9,10}

One method used to bring standardization is to use computers in guiding physicians. This has been used

effectively in ordering more complex items such as TPN.¹¹ By knowing the patient's sex, age, height, and weight and using the Harris-Benedict equations, a computer can estimate caloric needs along with a standard mixture of proteins, lipids, and carbohydrates. Also, elements such as the diagnosis, stress, and organ function can be factored in as determined by the nutritional experts who designed the program. The physician is given the option of modifying the solution but begins at a starting point that is standardized for the patient's needs. This saves the physician time and effort and reduces errors made by physicians inexperienced in ordering TPN. Electrolyte concentrations are then suggested based on the patient's latest serum values. The physician can select the suggested package or modify it. If the physician selects incompatible or dangerous concentrations, the computer sends an alert. Then standard nursing procedures and monitoring are automatically ordered, such as daily intake and output, weights, and every six hours urine glucose checks. Thus by using the computer, subtle control of care delivery is maintained through indirect expert guidance or critiquing. The number of calories, composition of nutrients, the electrolytes, and nursing care related to the TPN are controlled to some degree and the inventory of products reduced.¹¹ Similar programs for antibiotic ordering^{12,13} and blood banking¹⁴ have also been developed.

Computer-assisted orders can also improve quality assurance measures because specific information, such as the indication for transfusion, can be recorded for audit purposes¹⁴ and order overrides can be reviewed later for appropriateness. Complications can be reviewed to check logic errors and deficiencies in the computer guidance. Thus standardization facilitates identification of problems and allows potential solutions to be proposed and validated.

The computer-guided TPN orders are flexible enough to allow the individual physician to maintain control and feel in charge. If designed properly these and similar orders can assist physicians and make their task easier, thus enticing compliance. A more severe type of control can be imposed for specific purposes, but requires much coordination and cooperation to introduce. For research purposes detailed protocols have been developed that maintain tight control of the process of care.^{9,10,14} Experience with and acceptance of such control is limited and usually resisted by the medical staff who have been schooled to make decisions tailored to the needs of the individual patient and clinical situation, and feel standardization of practice would be detrimental to good care. The proof of such logic is lacking, and many authors are challenging it by demonstrating the inconsistencies in medical practice and decision making.⁷ They also point

out that because of this mind set we are unsure of the benefit of much of the care we now deliver.⁷ The use of rigid computerized protocols permits control of the process of care in such a way that it will provide answers to many difficult questions in medical care.

WHAT MUST HEALTH-CARE PROVIDERS AND MEDICAL SOCIETIES DO?

In order to improve health care, providers and medical societies must (1) begin to shift the paradigms and attitudes of health-care providers. Credible leaders must champion the cause; (2) establish methods of practice improvement that are scientifically sound and statistically defensible; (3) establish clinical data systems with reliable data capture, longitudinal records and the ability to measure outcomes and costs; (4) share successes through credible mechanisms; (5) teach the techniques and methodology to others; (6) influence politicians and bureaucrats to not inhibit the quality movement by inappropriate regulations and economic constraints; (7) promote team building and collaboration across disciplines; and (8) educate and influence administrators and accountants that quality is the key and not to focus on budget and FTEs. □

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