ON THE CALIBRATION OF ARTIFACTS

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Blood pressure is a function of the way it is measured. There is no rigid correspondence between pressure measured directly in an artery and pressure determined indirectly [1]; and it was long ago shown that the real pressure in the arteries is different from place to place, the systolic pressure generally being lower centrally and higher peripherally [2]. (There persists a conspiracy to act as though these inconvenient measurement dissonances simply do not exist.)

When we pretend to "measure" the blood pressure by any of the indirect methods, we are simply calibrating a succession of artifacts: Sound, with the Korotkoff technique employing Riva- Rocci's cuff; alterations in pulsatile volume, in the case of most automated techniques. The numerical value one assigns to a given artifact depends upon the yardstick employed and upon the empirical criteria for selecting end-points. Even if inclined to inquire, however, anesthesiologists and others using automated blood pressure measuring devices may have difficulty finding out how the devices work (select endpoints), let alone be able to acquire some estimate of "accuracy" or comparability with other devices of the same genre [3].

The inscription of values for blood pressure that may not be reproducible fortunately does not make much difference in the management of most surgical patients. This is because the blood pressure in and of itself is not the condition toward which therapy must be directed. The patient undergoing surgery either has a palpable pulse or he does not; gradations in between are largely irrelevant, except as way points establishing trends. Still "beat-to-beat accuracy," "control," and "precision" are buzzwords found in the text pages, as well as in the ads of our journals, and "stability" of the patient's blood pressure has been proposed as a measure of the quality of care provided by the anesthetist. It may be true that charts depicting unstable blood pressure are more likely to be associated with less favorable outcomes; but, there is no more reason to impute a causal relation than to claim that administration of four antibiotics is the *cause* of a uniformly grim prognosis.

In other realms of medicine, however, reproducibility of measurement is of signal importance. Reproducibility becomes essential, first, when it is deemed prudent or instructive to establish a norm. Reproducibility continues to be essential when there follows a perceived reason to determine whether, and to what degree, deviation from that norm has a predictable effect on another

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important observable variable, such as longevity. If such an effect is, in fact, observed, then deviation from the norm may legitimately be viewed as "disease." The imports of definition of the norm, and of reproducibility in measurement, are further amplified if an effective treatment is discovered for subjects exhibiting deviations from the norm.

In 1903, long before hypertension was afforded recognition as a pathological condition, Theodore Janeway of New York City was systematically recording the blood pressures of the patients in his large office practice. Coming to recognize that many patients with elevated blood pressure manifested evidence of both heart disease and generalized vascular disease, he coined the diagnosis "hypertensive cardiovascular disease" [4]. Still, for nearly half a century after Janeway, hypertension was not clearly recognized as an abnormal condition. Indeed, by 1930, Cushing would sarcastically question whether his introduction of the sphygmomanometer into clinical practice "has done more than harm," having "led to the uncovering of the diseases (God save the mark!) of hypertension and hypotension, which has vastly added to the number of neurasthenics in the world" [5]. Disease or not, there was no treatment for elevated blood pressure. Nonetheless, perhaps because of that hypochondriacal bent lamented by Cushing, and because the ritual was one of the few procedural interventions allowed the office practitioner, the "taking" of the blood pressure became a necessary rite in the physician–patient encounter, conferring "power upon the performer and grace upon the recipient" [6].

By the end of the 1930s, the emerging discipline of electrocardiography had been given a great boost when a committee of the American Heart Association under the chairmanship of Frank N. Wilson agreed on a standard placement for precordial leads. Their effort had been undertaken in collaboration with the Cardiac Society of Great Britain and Ireland. A direct effect was that the electrical artifacts being calibrated on both sides of the Atlantic became comparable; study of the meaning of these artifacts could only become immensely more rewarding [7]. Shortly afterward, a similar effort was undertaken with respect to measurement of blood pressure. There was no agreement on what constituted "normal" blood pressure; but, it seemed prudent at least to come to an agreement on *how* blood pressure should be measured. Accordingly, a committee under Irving S. Wright, working with a similar group across the Atlantic, published in 1939 the first "recommendation" for the technique of measurement of blood pressure employing a sphygmomanometer and stethoscope.

There was a growing perception that substantially elevated blood pressure might be problematical for those afflicted. Still, the brilliant Soma Weiss, whose untimely death on January 31, 1942, robbed Boston's Peter Bent Brigham Hospital of its young Physician-in-Chief, was numbered among those who cautioned that lowering of elevated blood pressure might interfere with perfusion of vital organs, particularly the kidneys [4]. (A half century later the same mechanistic views, unsupported by data, continue to be bruited in temples of academic medicine.) Besides, many subjects with elevated blood pressure lived long lives; and most patients with very high blood pressure had virtually no associated symptoms until shortly before their deaths. As Comroe has pointed out, President Franklin D. Roosevelt certainly had access to the best medical facilities in the world; but, "hypertension" was yet to be recognized as a disease. Besides, there was no treatment. Roosevelt's blood pressure had been known to be elevated since the late 1930s, and was recorded as 260/150 on November 27, 1944 [4]. The President had an episode of heart failure that year, but then returned to grueling international travel in the closing months of World War II. With his blood pressure recorded in the 300 range, Roosevelt would die of a massive stroke on April 12, 1945.

Following the end of the war in 1945, systematic study of the natural history of blood pressure elevation came to be pursued with increasing vigor. The Framingham Heart Study, continuing to this day, was started in 1948 [8]. It was not until as recently as 1959, however, that actuarial studies such as that sponsored by 26 insurance companies—and involving several million patients—clearly showed that elevated blood pressure was associated with decreased longevity [9].

Still, what could be done? Surgical therapies were draconian and marginally effective. Medical intervention consisted of phenobarbital and rest. The dusting off of rauwolfia in the early 1950s produced the first oral antihypertensive therapy useful in office practice; but reserpine was an inconstant remedy associated with bothersome side effects. With the advent of chlorothiazide in 1957, initially promoted as the first effective oral antidiuretic, this arena of medicine changed dramatically. Hypertension became a truly treatable disease, adding both comfort and longevity to the lives of thousands.

"The first Dinamap (Model 825) was introduced in early 1976 and measured only mean arterial pressure..." [10]. Up until that time, there had been no generally applicable way of measuring blood pressure except by stethoscope and manually operated sphygmomanometer. Soon there was a profusion of automated devices available not only to the medical profession, but to the

public, as well. The devices provided numbers. But what did those numbers mean? To what degree might the numbers be comparable to blood pressure values determined the time-honored way? Should the results even be expected to be comparable? Though some devices employed electro-acoustic sensors, virtually all the market survivors employed some form of oscillometry. Criteria for identifying end-points were far from uniform, however. Some manufacturers used appearance of pulsations of monotonously ascending amplitude, and disappearance of pulsations of monotonously descending amplitude, as indicators for systolic and diastolic pressures. Others looked at maximum oscillation, which is said to indicate mean pressure, and then assigned wholly arbitrary fractions of that amplitude as representing systolic and diastolic pressure [10].

In 1979, Cesar Caceres reported that, "About 1 year ago, David Link, director of the Bureau of Medical Devices, Food and Drug Administration, requested AAMI [The Association for the Advancement of Medical Instrumentation] to consider developing a standard for sphygmomanometers. The request was due primarily to the increasing use of such instruments by patients at home but also to the rapid increase of automated sphygmomanometers in a variety of public settings . . ." [11]. Similar concerns evolved overseas. This time, however, the international collaboration that graced the standardization of precordial electrodes and of sphygmomanometric blood pressure did not materialize. From a perspective substantially different from that of the US effort, the British Hypertension Society developed a standard on its own [12]. Today, before the European Committee for Standardization, there is still a third proposal.

As Webb observed in 1980, ". . . Since the observed data on diagnosis and treatment are based on the auscultatory measurement of blood pressure, it has become, in its own right, the true standard of hypertension . . ." [13]. It is still not clear, however, even after nearly two decades of throwing words, charts, and money at the issue, whether *any* automated measurement system serves up numbers that are directly comparable to the time-honored manual technique, nor that treatment criteria based on conclusions derived from the great mass of studies based on American Heart Association measurement criteria are transferable to patients whose "hypertension" has been diagnosed by a machine. This is a consideration of no little importance. A particular number comes to define those who are deemed appropriate to be brought under therapy, and those who are not. Webb cites the estimate that, "Each fall of 5 mm Hg in the accepted definition of high blood pressure doubles the number of patients requiring treatment . . ." [13]. More than that (even if the diagnostic criteria are constant), differences in measurement may also translate into thousands of patients and millions of dollars of drug therapy and medical supervision. Reproducibility of measurement, then, becomes critical; the relevance of a device under test compared to numbers presented by "the gold standard," the mercury manometer, is essential.

There is more: Although automation avoids the pitfall of observer bias, it generates a whole host of new problems. Will the device provide reproducible readings on other than sedentary patients? Will the device work at all under other conditions reasonably attendant upon its use: During stress testing? Rescue operations? Or even critical care applications? Under what conditions is it likely to fail? Or give a wrong reading? Is an automated device necessary in the first place? ". . . Before spending money on automated equipment the clinical investigator must weigh the attraction of automation carefully against the tried, accurate, and inexpensive, if less glamorous, manual technique with a mercury sphygmomanometer. Potential purchasers of automated equipment should examine critically the claims by manufacturers, demand evidence of reputable independent assessment, and then decide if the additional cost is justified" [14]. How are all these questions to be addressed?

In this issue of *Journal of Clinical Monitoring,* Iyriboz and Hearon propose a comprehensive approach to evaluation of all the issues [15]. This document is innovative; it is unique. The authors provide critiques and a concordance of the three extant ad hoc standards. Here is essential knowledge for all in the field: manufacturers, especially those looking at cosmopolitan markets; outfitters for military and civilian rescue and medical facilities; purchasing departments; clinicians; and, notably, the FDA. Relevant aspects of those three evolving standards, each viewing the issues from somewhat different perspectives, are then melded into a comprehensive scheme for testing and validation. On first encounter, the paper may be found intimidating. Far from being gratuitously Byzantine, however, the proposed test methodology sets up tiers of qualifications. If the devices do not make it over the first hurdle, they need be considered no further.

The bibliography is encyclopedic and catholic. Noted, for example, is inclusion of a review from *Consumer Reports,* one of the best available on the subject. Consolidating these references is a great service to manufacturers, students, and regulators; in the bibliography can be found a large part of the "required reading" for anyone who pretends to participate seriously in this field.

This paper should generate controversy. The "surrogate arm," for example, which the authors regard as "a viable option" and which comes from a most-respected source, strikes me as diversionary, if not a figment out of *The Stepford Wives*. But controversy can breed healthy progress. And, the fact is that at the present time out in the world of testing and use, there is no definitive model or test methodology for the validation of the most ubiquitous device in contemporary medical practice, second only to the stethoscope. Users, clinical engineers, the FDA, and conscientious manufacturers need criteria for the delineation of practical goals. The scheme here proposed might not be *the* best or definitive protocol; but, it offers a model others might emulate or refine. For the present, it establishes the benchmark against which competing proposals must be judged.

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The editors of the *Journal of Clinical Monitoring* wish to thank the following ad hoc consultants for making available their expert knowledge in reviews of manuscripts. We realize that these reviews take time away from schedules that are already very busy and would like to show our appreciation.

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