Stories about Blood Pressure Measurement. Labarthe-Blackburn interview June 2009

DL:: Did you ever know Arthur Ruskin?

HB:: I've heard the name, but I didn't know him.

DL:: He was at the Medical Branch of U.T. in Galveston and made a marvelous collection of transcribed original works called "Classics in Arterial Hypertension" And so he has the story of Stephen Hales. – And he has something about Poiseulle and the sphygmomanometer. He cites some early works around 1900, not long after Korotkoff, that talked about: what people thought about blood pressure at the time. So… I'm at a point now where I can begin sort of delving into this stuff which is really exciting and I'm really looking forward to it.

HB: Yeah that's great. You already have a good deal about the history but that will add color to it.

DL: Yeah exactly because color is what it needs and I follow our editor's notes attentively and realize that it's about the story that really passes muster with her.

HB: Yeah that's right

DL: So I understand that and I look forward to it. One thing I did also find on the blood pressure devices was a paper that Labarthe, Hawkins, and Remington did based on the HDFP evaluation of some of the early devices.

HB: I remember you did that.

DL: Some not yet marketed automated devices and so there are some stories in there too. And you can bring that up to date

DL: Right. I met accidentally at Scientific Sessions at American Heart, last fall, the people that I hadn't run into in years from Hawksley who were the makers of the random zero device. Well actually the Baum Company that bought Hawksley and is now dealing with the problem that regulatory action is in many states taking mercury out of the environment and they can't use mercury sphygmomanometers anymore.

HB: Wow

DL: So what happens to the standardization of blood pressure measurement? It's cut loose from its anchor and floats with these many devices.

HB: Wow

DL: So it's an interesting problem. It's as though we decided to tell time without Greenwich you know.

HB: That's interesting. Who would have thunk it? I think its ridiculous isn't it?

DL: Well it is. It's just getting swept up in a concern about mercury in tuna or something.

HB: Which I don't know much about. I understand most of it is mercury of natural origin and not human origin

DL: Yeah and I understand the mercury that fish carry around is not in a toxic form. Anyway. It's good will gone awry.

HB: I'm afraid it's giving a bad name to some of the health promotion efforts about fishes.

DL: There was a wonderful guy, I'm pretty sure his name was Leonard Goldwater. He was an environmental public health type who when I was in medical school came to visit and be a visiting lecturer and talked about environmental public health and I remember

one of the things he said was if I were a tuna I'd be suing someone for defamation of character

HB: That's interesting. How long ago was that?

DL: When I was in medical school.

HB: That's remarkable.

Some 40 or 45 years ago I guess.

HB: The notion was the mercury in tuna wasn't in a toxic form and tuna were getting a bad rap for it.

DL: So I suppose there are people who think that those of us who have been measuring blood pressure for years are mad hatters by now, or something

HB: Well I often wondered about the tons of mercury that spilled in the laboratory of physiological hygiene with the various gas measurements down in the work areas that we were exposed to for hours and days on end. The lab and personnel have never been tested.

DL: Anyway I'm not sure how far you want to get into the device business at the moment but we can talk a little about that a little if you like

HB: I would like

DL: I recall, and much of this is sort of coming back to mind as I was thinking about our conversation, that the Criteria and Methods Committee in the American Heart Association Council on Epidemiology had interest in this question. Epstein and then later finally... Oh I'm not sure who all else, certainly a number of others in the Council was on that Committee and the question was, how can methods be standardized to support

epidemiologic studies? One of the key questions was the measurement of blood pressure. I'm not sure if that Committee was the sole authority behind the American Heart recommendation for blood pressure measurements in those years, 1960's and beyond. I think the 1st AHA recommendation of blood pressure measurement methods was in 1939. I recall that over the years revisions and updates usually for the purpose of revising the decision about diastolic blood pressure - it should be 5th phase or it should be 4th phase or it should be 5th phase. Every few years the decision flip-flopped and they put out a new edition.

But one of the questions was about the devices as they were becoming available, and it was questioned whether they really gave readings comparable to the mercury sphygmomanometer. One of the sort of philosophical questions behind all that was, given the shortcomings that were well known about the mercury sphygmomanometer and indirect auscultatory measurement of blood pressure, what if an automated method were better? Was the conventional auscultatory method the gold standard against which these others should be evaluated or not?

And all of this came to a head in planning for HDFP because there were alternative methods that could be considered and the question was what should be the chosen method for blood pressure measurement in this new, presumably ground breaking, trial that would kind of set the standard for methods in the future for public health purposes?

HB: Is that when you did your study of devices?

DL: That's when we did the study. It was about deciding what was the best choice of blood pressure measurement methods and so we got started on this in early '72 as HDFP planning was getting underway and the question was what about the plain old mercury

sphygmomanometer. What about the London School of Hygiene machine, which I think by this time morphed into the Random Zero device. There was a company – I'm not sure of the manufacturer - the brand name was called Arteriosonde and the Arteriosonde had a couple different models. One was much simpler than another and one was more elaborate and certainly more expensive with lots of bells and whistles. Ed Kass was advocating a machine that was developed in Boston that was thought to have some advantages, and then there was something called Physiometrics that you may remember. It had a rotating graphic soft paper disc and the recorder pen would mark the fluctuations of corresponding auscultatory sounds when the pressure was being reduced and then you would just do a reading of these paper discs.

So each one had a certain advantage of its own. Even Sears had one that was being marketed for home blood pressure readings even back then. And I think the really genius behind the study was it went beyond the question of comparing against the standard mercury manometer. It was decided to test two devices, two units of every device so not only could you tell whether Arteriosonde 1010 departed significantly from the standard technique, but you could tell whether two Arteriosonde 1010s agreed with each other and I don't think anyone had ever done that kind of evaluation of these before.

So we got these machines together and a good friend, Dick Remington, designed what he called a Graeco-Latin Square design with random allocation of machines to starting points and so a standard number of readings when taken on each device and there were about three replications of this.

HB: Was the patient lying supine or seated?

DL: Supine, so we recruited about 30 people maybe -- to be the subjects and we didn't go out of the way to find people with a known range of blood pressures. They were basically ambulatory healthy people and of course we used the best available training methods for the observers using the mercury sphygmomanometer …. And that goes back to the other part of the story which was that the real advance in blood pressure measurement during the 50's and 60's had been the works of Geoffrey Rose and later, with him, Ron Prineas, who had developed an audio tape method to test the accuracy of an observer in timing the sounds so that…

HB: Was it you that told me the story about Dave Rutstein or did Ron tell me?

DL: That must be Ron's story because I don't know it.

HB: Ok. I don't know it but apparently he got quite agitated when his poor performance on the tape was exposed.

DL: I remember that story now and I would enjoy it in a conversation with Ron to freshen that memory. Geoffrey, and Ron working with him, had developed a tape and the tape was a recording of Korotkoff sounds in a more or less typical auscultatory sequence and the trick was you would turn on the tape and get a certain signal which came from Ron Prineas. The trainee was to actuate exactly simultaneously two stop watches so there was a count down and it was a count down with a thick Australian accent which lots of people didn't understand. And it wasn't the highest quality voice recording but it went something like THREE… TWO…ONE… start.

It was a bang, actually like a tap on the table, and at that point the trainee was to actuate two stop watches -- you were to listen until the systolic criterion was met (and there is a little nuance to defining that) but at that point the observer was to click the first stop

watch and that would capture the starting time, presumably the systolic pressure; then at a certain point which was to correspond to the diastolic end point -- the observer would click the second stop watch and that would be then a verifiable reading of the observer's performance because of course the first stop watch was to be clicked at a certain time elapsed from the signal from Ron Prineas and the second watch was to be stopped at the point where the diastolic end point was reached.

Now this isn't the film, that had a different technique, but it was just the audio tape -- so we trained people to use that and they were the standard in this Graeco-Latin Square experiment.

Well one by one the automated devices fell away and off the list. They broke down. Or the cuffs would inflate mercilessly around the arm without stopping, producing pain and ecchymoses under the cuff. Any number of engineering difficulties occurred which immediately disqualified many of these devices, particularly the big Arteriosonde which cost $5000 and didn't operate after about the 5th reading.

So anyway, the leading candidates when all was said and done were the standard mercury sphygmomanometer, and of course closely allied to it was the random zero – the same issues as far as the mercury column and reading the column were concerned but with the actual values obscured to the reader.

So that was the choice – the random zero was going to be the technique, but it required the same training as the standard mercury manometer. It was just a little more complicated. You had to take another step at the beginning, since it wouldn't show on the random zero how high the systolic pressure actually was by looking at the manometer. But you needed to inflate it higher than the actual participants' systolic pressure. You

had to crank it up quite a ways to be sure you were above it and then listen for the appearance of the sounds, know that was systolic, and without changing the manometer you'd then go ahead and do the actual readings. So that was the basis for choosing the random zero spygmanometer which was adapted for HDFP because it needed a wider range of zeros. Well let's see that's not true. It needed a narrower range of zeros so you wouldn't have to inflate the pressure so high to be sure that your blinded reading was above the true systolic. But having made that decision, knowing that then the observers across the whole 14 centers of HDFP would need to be standardized in their performance, we convened a training session in Houston just before the start of recruitment and this was to train clinic supervisors in the protocols they would have to enforce, the observers in all the things they would have to record by measuring blood pressure and height and weight and doing the interview questionnaire and all the rest. Clearly a key part of it, and the one that probably had the greatest anxiety attached to it, was training and certification of the blood pressure observers.

So we had a hotel in downtown Houston in a large room, large tables and many chairs, recording devices, tape recorders. Back in those days for these cassette tapes we reproduced the tapes -- the Prineas-Rose-tapes -- so that every station would have its own audio cassette and they had head phones so they could listen to the sounds and everything was "hunkie dorie" as we started the training session. There were probably around about 30 people in the room doing their training. Before the morning got very far along we learned that there was a technical problem we hadn't planned for and that was that the audio cassette players didn't play at the same speed. Since they didn't play at the same

speed the time interval that an observer would record if correct would not be the same time from one observer to another cause they were playing on different machines.

Well you couldn't evaluate the accuracy of timing of any given observer because you didn't know what their recorder was doing. Someone might say it was 30 seconds before the systolic came. Someone else might say it was 20 and maybe that was so, on the players they were listening to, but which was correct? So we frantically got in touch with Geoffrey Rose. I telephoned and I couldn't reach Geoffrey. He was not in the office in London, but I left a message with his secretary and the message was "we need to know the standard time interval between the mark from Ronald Prineas and the true onset of systolic sounds".

Before the day was out we had what may have been the shortest telegram in history. It was addressed to me at the hotel and it said, "26.3". So with that information we could calibrate, but it meant that we would need an army of the people from the Coordinating Center in the back of the room to recalculate and calibrate the correct times to the 26.3 that it was supposed to be. And it was a nightmare, but we managed to get through it.

Now technically you'd just have all different ear pieces to the same apparatus.

Well in the later development that became sort of the recertification training tape for HDFP and the subsequent trials was the video tape that actually showed the mercury column accompanied by the sounds and allowed standardization of observers that way. It was used in the Seminars for years as sort of a demonstration of measurement standardization.

HB: That's marvelous. It would be very nice if you could interview Ron Prineas and I could interview Dot Buckingham -- I just saw her last week.

DL: Did you? Well there's another twist to the story that you may remember. Given the high level of anxiety among the people being trained and everybody's discomfort about being certified through this process, we were in some desperate need of a winner, at the end of the first day, to demonstrate clearly that this actually could be done. It wasn't an impossible task – it wasn't totally unreasonable. It could be achieved and as it happened there was a staff member from Davis – Laurie Fleishman - who was very bright – very capable person who as we did the calculations in the back of the room seemed clearly to be the first person who had actually passed the test. So we quickly declared her a winner and announced the triumph of her success and concluded the day with everyone believing that this actually was possible and the next wave of people came in the next day and did it. Only into the second day did someone who was in a fit of quality control recheck the numbers from the first day and found out she actually had not passed. And the question then was, do we let it go or do we redo it? We let her know quietly that it would be necessary for her to actually do it again. Which she did and passed and everybody was happy.

HB: That's a beautiful story.

So that's the blood pressure standardization story.

It would be nice to get with Ron. Would you like to interview him? I think he's available these days.

I would be delighted to

HB: They're sitting right where they were in Winston Salem. They sold his whole book collection. So he's spending most of his time taking care of Julie and still consults

actively at the center. I'll send you his number. That will make a good story and we'll get it on the web.

HB: Do you want to say anything about continuous blood pressure measurement?

DL: I'll be able to. I spent some time working with a guy in Houston, Ron Portman who is one of the real advocates of the ambulatory blood pressure measurement in kids specifically and he put together a modest symposium to talk about this. And produced proceedings and so on. I'll be glad to look into that. And there's this more recent.

Fair enough. I've had conversations not in the recent months but a couple years ago with your colleague in Minnesota about chronobiology.

HB: Yeah every few years Franz Halberg pops up and we deal with him.

DL: Yeah well, and the poor guy was just pleading for someone to work with him and carry the work forward and so on. He had a very close working relationship with a faculty colleague of mine in Houston, Mike Smolensky, and I think Mike may have worked with him first in Minnesota before Mike came to Houston and Mike was very interested in chronobiology and the issues of shift work and effects on various biological clocks and so forth.

HB: Very good stuff – but he's just impossibly intense to deal with

DL: And the other thing on the continuous blood pressure is this whole business about night/ day differences or where there's black/white differences in the nighttime spikes and that kind of thing. Which is kinda like angels on a pin.

HB: I think that makes a great story…. With that and with what we have we don't need to do much more with that.

DL: There's a questions that I've been interesting in -- I'm just sort of curious about and haven't quite tracked down and it would be of interest to a couple of stories. The whole business about the Society of Actuaries. The impression that I've always had was that in a remarkably short time after Korotkoff the life insurance industry picked up measurement of blood pressure and it became – within the spheres of the life insurance industry universal in almost no time. And as early as 1913 there was a Society of Actuaries study that talked about blood pressure and mortality. I just haven't had any time to track any of that down and I didn't know if you would have any of that in your archives or not.

HB: The first Build and BP report was in November 1978 and another big one in 1959. Anyway that would just be fun to look into.

It would be fun. I'm not sure how much time we should spend on that

DL: And then there's the Army study of Levy, Stroud and White - there's someone else in that group. There's got to be some interesting documentation behind that but this was a lot of the early stuff about transient hypertension and the idea that blood pressure fluctuation was bad for you and so on

HB: Oh dear. A book in itself. Didn't you do some stuff on lability?

DL: Well thanks to Jerry Stamler I was looking at the question of whether lability of pressure added. or conferred risks of mortality beyond the average blood pressure level itself and thanks to data from Jerry and the Chicago Gas Company for a series of examinations and subsequent survival -- turned out that what mattered was the average blood pressure level over the period not whether it was rising or falling or fluctuating

beyond the standard deviation or anything else. That higher blood pressure wasn't good for you was the message.

HB: Yeah not yet wholly accepted. A word about how we deal with systematic error in measuring blood pressure trends in populations and that sort of thing. Do you have any comment on that? Because I don't want to go into details about when you hire and fire a blood pressure measurement person. But certainly we found difference between survey groups, between survey clinics as well as between individuals and how we try to put that together when you're recording all the data from the study. Have you worked with that?

DL: Yeah. We did in HDFP. We checked for digit preference which was taken to be a lapse of diligence in doing the readings and called for retraining. We did the same thing in project HeartBeat! We used the video tapes and trained people and monitored the ending digits and so forth.

HB: I'm talking about something after you've already done all the training and hired people and retrained them.

Can you correct them? Our judgment was we didn't have a way to do that. It's hard to know what the truth is if you don't have the data

HB: I have to look up some of Paul McGovern's stuff in MHS. He could do it and we did the same thing for cholesterol trends in our Minnesota organization. I'll have to explore that ok.

Do you have any photographs of any of these scenes in this area?

DL: It's possible and I have an opportunity coming up to sort of make one last pass through the long accumulated slides and so on before tossing what's tossable. So I'll be on the look out for that.

HB: It's very rare to find any good survey situation or experimental situation or any clinic situations that make a good picture. But if you have notable people and notable occasions would be nice at least put them on the web. If they are suitable for printing.

DL: I'll keep an eye out.

I think were okay for the ancient history if we get into the Ruskin book.

I wish I could remember the name of the guy from Physiometrics. He hated us cause we sank his machine.

HB: Yeah that's right. I think we sank the Arteriosonde too.

DL: I don't think the Arteriosonde did very well after that. And then the guy from Physiometrics just hated us. He accused us of phonying the data and all that I don't know why he thought we would do that. But Gerald Berenson used the Physiometrics for Bogalusa and thought it was wonderful. Maybe they were lucky -- I don't know.

And then there was Yamori who you remember very well. Yamori asked us to evaluate the Japanese machine that he wanted to use in his big study. His big global study. And we evaluated and found it wanting and he then went ahead and adopted it based on our favorable evaluation which……

HB: There was clearly a "misunderstanding"

DL: We still have a little more to do on some of the stories haven't we?

HB: I enjoyed your stories.

DL: Thank you very much. I look forward to really digging in and being useful.

END

Addendum. HB: I have copies of the insurance industry Build and Blood Pressure Studies of 1929, 1959, 1979, and the Medical Impairment Studies of 1938 and 1983.

The MAMI, Medico-Actuarial Mortality investigation was published in 5 volumes from 1912 to 1914, covering insurance issued from 1885-1908! I don't know how or if they treated BP. My volume of the Medical Impairment Study of 1929 covers 1909-1927 when the "new" medical coding was put into effect. All was done, they report, with "up to date perforating machines" in 1.1 million cases and 41,000 deaths followed an average of 4.7 years of insureds aged at entry 40.2, 1/3 of whom were substandard insureds. Interestingly they used 3 cuts of Systolic BP over the average, which was 120-125 (no diastolic), 125/135/145. HB: