



## Accidents of life

---

You are master of your destiny, so you think, but much of life is shaped by things you have no control over.

By far, the biggest event of my life is detailed elsewhere in a chapter entitled “The Tupperware Party” in *Stories and Essays from Klinkapunk*. It led to nearly 60 years of married life and three wonderful daughters.

The accounts below are of other accidents serving to shape my life.

### **When I was born**

I had nothing to do with when I was born, yet the reality is that the timing was exquisite for what I ended up being – a trialist.

By the time I was ready to go out in the world, I ended up, quite by accident, being involved in trials. Not trials like in courtrooms, but rather trials done on people – clinical trials.

Trials, to be sure, were not new when I happened along. Indeed, the first modern day equivalent of a trial took place in 1747 on board a ship at sea. But trials when I came along were still rarities, not widely practiced or valued.

## Accidents of life

---

Post WW II prosperity led to major increases in NIH funding for research including clinical trials. The funding gave rise to several large-scale trials starting in 1960 and continuing into the 1980s.

Through no fault of my own, I became an “expert” in the design and conduct of trials – “expert”, in my day, jocularly characterized as a horses ass, with a briefcase full of slides, over 100 miles from home.

Professionally, I grew up with the rise of trials as an academic activity. That timing served me well. It led to creation of a journal devoted to trials, several texts focused on design and conduct of trials, and teaching and training graduate students in trials.

The sad reality is that I may now be seeing the decline of trials as an academic career. Trials have been hijacked by regulators and funding agencies and by people who see trialists primarily as data generators for meta-analysts.

### **The term paper**

When I was in high school, English seemed irrelevant (how stupid of me). Certainly, at the time I had no idea that I would end up spending a lot of time "writing" and certainly no idea that eventually I would be writing textbooks.

In 11<sup>th</sup> grade English we had to do a term paper on a topic of our choosing. I chose television as my topic. True to my JIT (just in time) nature I did not start on the paper until within days of it being due.

I knew I needed to "research" the topic, but I procrastinated. By the time I got to the assignment the deadline was hard on me. It was too late to go to the library for books on the subject so I was reduced to what I could find in encyclopedias at home.

Eventually I ended up with a piece that I thought was good. I handed it in with pride expecting an A. When I got it back I was dumbfounded. Across 1<sup>st</sup> page Miss Hook had written "Plagiarism!" and below that a two inch "F". I had never seen the word before so I had no idea what she was talking about. I asked her why I got an

## Accidents of life

---

F. She said "You copied somebody else's words without attribution. That is plagiarism!"

Thank you Miss Hook for the F! I needed that given my career as a researcher and the importance of integrity in research.

### Highway building

When it came time to go off to college I was fixated on civil engineering. I wanted to build highways so I applied for admission to the school of engineering at the University of Minnesota. I was accepted with a caveat: Because of not having had some basic math courses that I should have had in high school, I would have to take and pass those for admission to the school. Undeterred, I registered in the College of Literatures and Arts until I could take the required math courses.

While I was waylaid I had a chance to observe engineering students. They looked to be a dreary lot. Slide rules strapped to their sides with glassy stares walking into trees. By the time I had the necessary prerequisites I had decided that I did not want to be an engineer!

Thank you Sleepy Eye High for not having had the necessary prerequisite math courses!

### Graduate school

Fast forward now to my senior year at the U of M. I am ready to graduate so I start hunting for a job. In those days they were easy to find. There were lines of stalls with representatives from all sorts of companies trying to entice you to sign on with them. Having an undergraduate degree in psychology I was a fit for Procter & Gamble. I signed on to move to Cincinnati to sell tooth paste, or whatever. It was settled. Cincinnati here I come.

About then I got word that the chair of the department of biostatistics, Jacob (Pete) Berman wanted to see me. What now?

As it turned out I had taken a biostatistics course in my senior year and knew I had done well enough to not be called on the carpet for that.

## Accidents of life

---

I went, albeit anxious. When I got there I learned the chair wanted to offer me a fellowship for graduate school in biostatistics. The fellowship covered tuition and provided a stipend as well. When I heard the proposal I remember saying, “Let me see if I have it straight. You are going to pay me to study. I think it is a bad idea. I don’t think I can pass the courses I would have to take.”

His reply: “You study. Leave the worrying to me”.

That was the end of my career selling tooth paste and the beginning of my career as a biostatistician-trialist.

Thank you Pete!

### **Don’t bother me with job offers**

Now it is fall of 1960. I have finished my course work for my PhD in biostatistics and started work on my doctoral dissertation. About then I am told that there is this person named Klimt who is joining the University and looking for someone to work with him on a project that eventually came to be called the University Group Diabetes Program (UGDP).

I run into Pete Berman and he tells me that mine is one of four names he gave Klimt as possible candidates for his job. I thanked him and filed it away.

Several weeks go by and Pete hunts me down. He tells me that Klimt has interviewed three of the candidates but had not seen this Meinert guy. I told Pete “Yes I know. I am not interested in a job. I want, first, to finish my dissertation. Then I will look for a job”.

I caught hell. I was told I was being rude not even talking to the man. Having no desire to be rude, I went for an interview, albeit reluctantly and without enthusiasm. Get it over with so I can continue my dissertation work.

The next thing I know I am sitting in an office on the 11<sup>th</sup> floor of the Mayo building next to Klimt working on the UGDP.

## Accidents of life

---

Thank you again Pete.

### **I am not interested in moving to Maryland**

By now I am three years into the UGDP; Klimt in one office and me in the other office. We are learning as we go since neither of us had experience running multicenter trials.

I did not know it, but there was a storm brewing between Klimt and the chair of the department. Let's just say their styles were different.

Things came to a head over a telephone cord.

As it turned out the telephone cord in Klimt's office was not long enough to reach his desk. Whenever he had to use the phone he had to lean far to the right. He had, on several occasions asked people in the department to fix the problem, but nothing happened.

So one day Klimt gets in his VW and heads to Radio Shack to pick up a cord. Then crawls under his desk and installs it.

Happy at last.

The next thing I see a few days later is Klimt and the department chair toe-to-toe growling at each other about – you guessed it – over the telephone cord.

A few days later Klimt shows up at our house to announce he is leaving. Going to the University of Maryland and wants me to come along.

No way. I still have my dissertation to finish and besides, we have no desire to live in Maryland. We are Midwesterners and intend to remain so.

So we move to Maryland.

A few days after we got there I am standing outside our abode. I say to my wife "We will stay a little while, but I do not want to wake up dead in Baltimore."

## Accidents of life

---

I will wake up dead in Baltimore.

### **You cannot live with trials alone**

I enjoyed my life as a trialist, but eventually I came to realize that I could not live by trials alone. I needed something else.

After having designed and implemented several multicenter trials I realized how similar they were even if the disease conditions differed. From a design point of view they needed the same things, but the groups doing them were isolated, basically reinventing the wheel. The yearning to learn from one another caused me to organize what came to be called “Meetings of Coordinating Centers”, held each year in May. Eventually, the activity took a fair amount of time and staff support. Enough time and staff support to earn the rebuke of Klimt. Interestingly, he embraced the activity when it ultimately gave rise to the Society for Clinical Trials and his membership on the first board of directors for the Society.

### **I am happy here**

Originally, when Klimt and I moved to Maryland we were located on the medical school campus of the University of Maryland. One of the things I missed after leaving Minnesota was being on a real university campus. A campus with grand buildings, grass to lay on and trees to sit under. The Maryland campus is a city campus squeezed between other buildings.

Eventually Klimt tired of university administrations and decided to move to space 3-4 miles north of the campus. Though closer to where he and I lived, I came to dislike the place. Too encumbering. Too isolated from all things university.

To begin with, I had an office there and an office on campus, but I soon learned two offices is one too many so I basically severed ties with the off campus location. I stayed involved in trials but from downtown.

Also, about when that was happening the department was in transition. The former chair left to go to the University of Washington and then we had acting chairs, me being one of those for a couple years.

## Accidents of life

---

Eventually there was a new chair appointed, not a friend of trials or of trialists. That was obvious, but he was blocks away in another building.

Happiness is relative. I was happy enough so I soldiered on until one day I got a call from Leon Gordis, chair of the Department of Epidemiology at Hopkins, telling me he wanted to come talk.

Come ahead.

When he arrived I learned he wanted me to move to Hopkins. I thanked him for the offer but said I was happy where I was. He said that I should think about it and that he would call me in a month or so to followup. By the time the month or so rolled by I was worried he would not call.

Thank you Leon for the call.

### **The Oxford University Press proposal**

Everybody in academia gets bitten by the “bug”.

I have learned to recognize bites of the “bug” infecting students. Sooner or later they show up in a dreamy state with glassy eyes talking about their future and goals. After a few minutes I say “Sounds like you have been bitten by the ‘bug’”.

“Bug?”

“Yes. The PhD bug.”

Hang around academia and you will, sooner or later, be bitten by some “bug”, in my case the desire to write a textbook on the design and conduct of trials. My “bug” hit when I was still at Maryland. I took a six month sabbatical to get started. By the time my sabbatical was over I had nothing to show for my effort, but the good news was that the “bug” was gone!

The desire to write a text was gone. Gone. Gone and good riddance.

## Accidents of life

---

But, alas, there is no immunity from the “bug”. I got my second infection after moving to Hopkins, after I started teaching a course on clinical trials.

One day I get a call from Abe Lilienfeld at Hopkins urging me to write a book on clinical trials. He was on the editorial board of the Oxford University Press and was commissioned to get a book on trials.

So. What the hell? Why not?

Happy to say that I finished that one.

Thank you Abe.

### **The training grant**

Sometime in the early 80s I got involved in the Glaucoma Laser Trial; a multicenter trial with us as the coordinating center. The project officer was Anita Suran. She became impressed with what we did and started urging me to apply for a training grant from the National Eye Institute of the NIH so we could teach others the art form.

Training grant? Who needs that? Trying to teach toads how to jump. It’s an empty set. If a toad knows how to jump there is nothing to teach and if it cannot jump it is not possible to teach it how to jump.

No training grant for me. Thank you.

So I got the training grant and trained students how to jump and in the process used it to create a center for clinical trials devoted to training toads how to jump.

Thank you Anita.

### **The Curtis Meinert Professorship**

For years we were the coordinating center for the Studies of Ocular Complications (SOCA). Over those years, because of joint NIH and industry funding, we were able



## Accidents of life

---

to sequencer money, ultimately about 2 million dollars. The money was used to buy computers and other supplies, not covered with NIH-funding.

Eventually, I learned what lottery winners learn; everybody wants your money. When I complained about the money vultures over beer and burgers at some low life place in Fells point with my former dean, Al Sommer, he would always be urging me to use the money to create a professorship in clinical trials to support a worthy persons in the school doing trials.

I thought it was a bad idea because once the School has the money you lose control.

So I did it.

Thank you Al. The money vultures are gone! Good riddance.

### **I am too old for this shit**

Sooner or later you realize the tank is near empty and you have passed the last filling stations. I keep “working” because it is better than just sitting.

Life gets heavy just sitting. There are only so many ways to do nothing. And writing more books? Who needs that?

So you can imagine what I said to a colleague of mine at Cedars Sinai in Los Angeles, Steve Piantadosi (now at Harvard), when he wanted me to co-edit a comprehensive work involving 150 authors entitled “Principles and Practice of Clinical Trials”.

I’ll do it!

---