Paper PD05

From Programmer to Patient, why it is good to be a Clinical Programmer when you are seriously ill.

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ABSTRACT

We spend many years working in the area of medical research, gaining knowledge and understanding in areas far beyond SAS programming. When a diagnosis of metastatic cancer happens, you are now on the other side, journeying through the patient side of medicine, with all its trials, decisions, treatments, experiences and outcomes. This paper will present three reasons why it is good to be a clinical programmer when you are seriously ill.

INTRODUCTION

A quick summary of my illness. I was playing archery in January 2016 and when taking down the large targets at the end of the session, I thought I had given myself a hernia. The GP sent me to a Hematologist who diagnosed Lymphoma as the tumours he had diagnosed were too big for anything else. A biopsy confirmed squamous cell cancer and after two months examinations, no primary tumour was found. I was offered four different chemotherapy regimes and decided on carboplatin/taxol. I had four cycles of this followed by a partial lymphectomy last September. No cancer was found in the removed nodes. After conflicting advice I did not have any radiotherapy and no other treatment followed. After several follow up scans, no further sign of cancer has been detected.

FIFTEEN DIFFERENT TYPES OF LYMPHOMA

The first diagnosis was of Lymphoma. The doctor gave it quite matter-of-factly, “of course it is Lymphoma, you don’t get tumours this size which are not Lymphoma.” I was moved straight out of the room with a nurse to perform some tests (the first of many blood labs and vital signs) still trying to digest this, legs shaking and trying not to faint.

I don’t remember getting home but I do remember that as soon as possible I got onto the internet to look up Lymphoma. What a huge amount of stuff there is. Locating a good website takes some time but with a clinical programmers background, it was easy to drop what was not useful. I found one website which listed about fifteen different types of lymphoma and their treatments. What joy to find some familiar drugs, drugs I have worked on in the past! This familiarity helped calm things and it was good to see how very effective some of these treatments were. Would I be taking one of these familiar drugs? A biopsy would show what type of cancer I had. So I went through, seeing what types of lymphoma were there. Some had cure rates of 95%, others were quite deadly. Slowly unease crept in. Familiar drugs or fatal outcome, what was my fate? Nervousness was overwhelming.

Then I used my training to look at the situation. Clinical programmers after all are very logical. I was considering fifteen different types of lymphoma but what was clear was that I only had one of these. Therefore I was worried about fourteen different things, which had absolutely nothing to do with me. I began to calm down. I went outside and moved a bench to the other end of the garden, which was the highest point available. From there I could observe the nearby rolling hills of Devon. At the end of the day I went and sat on the bench to watch the sunset unfold around me. Thankfully the sunset was brilliant for weeks and was not hidden by the usual cloud. I would sit there and watch the sunset and just be thankful that I could sit there and watch the sunset. So far, I did not feel ill, I felt totally healthy, was of sound mind and could sit in beautiful Devon with my family.

I spoke to a relative who was in charge of an Oncology day-ward, giving chemotherapy to over sixty patients every day. I asked her to forget the medical side and tell me if there was any difference between the patients who survived and those who died. She immediately said yes, those who were bright and chatty were the ones who survived, those more morose and introverted were the ones who died. So in this health situation, your mental attitude was going to go a long way to aiding your recovery. This gave me great comfort, I had spent years looking into Stress Relief techniques and was well aware of how to change your mental attitude. I could do something with this.

It took another two months, several biopsys and investigations before the doctors eventually gave up looking for a primary tumour. Nothing else was ever found apart from the two tumours in the lymph nodes. Biopsy showed squamous cell cancer but this type of cancer could be anywhere. This left a dilemma- you treat cancer according to what the primary tumour was and I had none. So what was my treatment?

CHOICE OF TREATMENT

In the U.K. it is the patient who decides what treatment is taken and they offered me four different chemotherapy regimes, two triple combinations and two double combinations. These were all old-fashioned chemotherapy regimes, I was now far away from the high tech biologicals I had worked on before.

So what to choose? A clinical programmer can easily go on the internet and start looking up relevant clinical trials. For the triple regimes I was shocked to see how very little trials had been done. For one regime I found only one trial of 30 patients with a 40% response rate. That was all. A response rate for tumours can be tumours disappearing, tumours shrinking or tumours just not growing any more. I wanted a complete response, the tumours disappearing and it seemed a big bet to risk my life on a treatment that had only been tested on 30 patients. The next triple regime was not much better. It only had one ongoing one-armed trial which had an interim analysis of 50 patients which showed that they had not achieved the desired response rate of 60% and had had to lower the doses because of adverse events (To compare these numbers, the smallest number of patients I ever saw in an NDA was 287). To be clear, both triple combinations were very nasty and would have entailed a week's hospitalization for every dose and I would not have been fit for work afterwards. Most unpleasant. The double combinations were better. The first was the standard treatment for squamous cell cancer, the second a common chemotherapy regime. Interestingly enough, different doctors that I had seen gave conflicting advice. The decision to make for me was easy- the evidence shown was that the cancer was squamous cell cancer, therefore I would choose the double regime which was the standard treatment (Note: later I met up with old friends in Germany who were doctors working with squamous cell cancer patients and they called it the, "Gold Standard" treatment. In other words, it was a good choice.

ONCOLOGIST MEETS CLINICAL PROGRAMMER

The main doctor I interacted with was the Oncologist and he was fine with this choice. He did not know quite how to react to a clinical programmer and was quite surprised when I asked to see the blood analysis printouts, but was happy to oblige and even organized that the nurses would print it out every time I came for my chemotherapy or check-ups. This was very helpful to me- the chemotherapy regime I was taking destroys your immune system and I could see how well it was recovering after each dose.

The Oncologist was rather shocked when I asked him about markers and then told me he was using a tumour marker called CEG which was not specific for squamous cell cancer but often indicated cancer activity. For me it was above normal levels. Every time I saw him after that he would give me the marker level and often gave me a graph, which showed it nicely dipping down back into normal levels. We got on very well and he would often ask me what was going on in clinical research. Whilst he can read all the literature, we have a different perspective on what is coming and I think he found that helpful.

So the chemotherapy was chosen. By this time the tumours were about the size of a chicken egg and a golf ball. They were not only visible, I often had to wear tracksuit trousers as my normal trousers no longer fitted. What is chemotherapy like? Most unpleasant. I was on a three week regime. A few days after the first treatment, complete body pain was there 24 hours a day. The worst was myalgia, muscle pain. It felt like someone was stabbing me with a black knife and often I would suddenly scream out loud at the sudden pain. I could use me anti-stress techniques to make things easier but this sudden onset was difficult to cope with. I had often seen myalgia on adverse event reports, now I had a bit more respect for the condition. Complete hair loss quickly followed. Difficult was that for a week in every cycle the immune system was disabled, so I had to be very careful not to meet anyone, in case I picked up any infection. That would have meant hospitalization but thankfully never occurred. The worst day was always the day before the next treatment, finding the courage to go back and do it all again.

THE OTHER SIDE OF STATISTICS

In the middle of this, I made a bad mistake. I looked up what the survival rate was, for metastatic cancer of unknown primary. What came out was that 55% of patients die within six months. This is a devastating statistic to read. I once read a newspaper article about a man who is dying of cancer. In fact he has been dying of cancer for a long time. You do get to meet quite a few other cancer patients when you are ill and this article made the observation that all those he knew who were told, "you only have two years to live", were fine until they came close to this deadline, then they quickly faded and died. So his advice was to avoid getting this type of information.

Of course, the people he knew could have been responding to their normal disease progression. But it can also be that the effects of learning, "you only have six months to live" are so strong that you cannot gain the energy to survive for longer. This is very much a mental battle.

What we produce in our work is statistics. What I found in my situation is that statistics are power things and are very difficult to ignore.

For me it was a horrible trap, like looking at a brick wall that is too high to climb. I needed help. And I got it.

I did not publicize my illness but a few colleagues got to know. All throughout I had offers of help to get in touch with Oncologists in pharma development. In fact, I cold have called on specialists in three different companies. What a huge support that was, simply to know that if you need it you can talk to some of the best cancer experts in the world. I never used it, for the rather obvious reason that my primary tumour type was not known, making any advice difficult.

For my current problem, I was in luck. A senior Oncology statistician was on holiday in Devon, only thirty minutes away from home. I went to meet her and her family. When I told her about the survival statistic, she quickly put the matter to rest, in a solid manner, “oh that’s just nonsense, it does not apply to you, it is for the cases where people are found to be absolutely covered in metastatic secondary’s, not just two. Forget it.” You are really struggling to survive in such situations, every ounce of energy focused on survival and to hear such comments was a huge relief. It did not just remove a stone from my heart, it tore down a brick wall.

I had further help from another statistician. Many years ago he had said to me, “just remember all the statistics in the world cannot tell you what will happen to one particular patient.” This statement is not only true, it is a very strong statement. I passed this on to several of the doctors/nurses I met and it was very interesting to see the way health care professionals reacted. Many of them were very active in keeping patients upbeat and optimistic and it was clear to them that here was another important piece of information to help keep patients going. While it did not get me out of my last predicament, it does leave you feeling free of the confinements of “statistical predictions”. Some doctors give predictions which too often come across as hard facts. This was also done to me, in a very negative way.

EVER MET A DOCTOR WHO IS TOTALLY CONVINCED OF HIS FACTS?

The next stage came with surgery. It was clear that the tumours had to come out, but I was met with a very enthusiastic surgeon who insisted that all the lymph nodes on the left had side of the groin should be removed and if I really wanted to be safe then all the lymph nodes of the right hand side should also be removed as well. I checked this. His course of treatment was correct, it is just there was a very large risk of lymph edema, or water on the leg. You remove all the lymph nodes and there is nothing left to remove excess fluid from your legs. This is a permanent side effect and has a big effect on your quality of life, for when your leg swells up with water any type of exercise is severely restricted. So here is a balance between risk of return of cancer and long-term side effects.

This was the hardest decision to make. Reasoning it through I decided to take the strategy that I would take the perspective of myself in five years time. Given the worst possible outcome and the best possible outcome, which decision would I least regret? It was clear that I did not want all the lymph nodes removed, I would accept the risk to take on a better quality of life.

The surgeon did not like this. Nearly all doctors I met were totally safety orientated, but they did not have to live with the long-term consequences of the decision. I did. The surgeon postponed the argument until the day of the surgery. We sat there dressed in surgeons green and patients gown arguing. I was told that if I went ahead with a partial lymph node removal I would definitely be back in front of the surgeon with a return of my cancer and that he might not be able to operate again because of too much scar material left by my current operation. At one point he walked out.

After my partial lymphectomy I only saw the surgeon directly after the operation, he did not visit me further in hospital. Note: the surgeon was very skilled and I have very little scar tissue.

The best news I had was that when the removed lymph nodes were examined under the microscope no cancer cells were found. The chemotherapy had done its work, final response was a CR (Complete Remission).

The medical machine moved on. At the surgeon’s insistence, I was asked to do radiotherapy. My oncologist arranged a meeting with a radiotherapist who, now warned to do her homework, brought printouts of literature with her. There were two different recommendations of whether to do radiotherapy in my case, both contradictory. Side effects would be the destruction of the remaining lymph nodes, as well as other further tissue damage in the area. My training switched in again. When I asked why the radiotherapy was recommended, the answer was to remove any remaining cancer cells that the surgery might have missed, on a microscopic level. However, if there were no cancer cells left in the effected lymph nodes, what was the likelihood that there were any further cancer cells “left behind”?

I did not have any radiotherapy, nor any other further treatment. I have had several scans since then and all have been clear and if the next scan is also clean I will have successfully passed through the critical first year, when most cancers return.

ADVANTAGES OF BEING A CLINICAL PROGRAMMER

We are all getting older and illness is nigh on inevitable. The good news is that our training and experience help us get through the experience. It takes a certain type of character to be a clinical programmer, attention to detail, stubbornness to get the outputs done on time etc, and this helps get through severe illness.

WE KNOW ABOUT CLINICAL TRIALS

The reason I wrote this paper was because I was given the option of multiple different treatments. In cancer you treat the primary tumour type and if this is not known then guess work is apparent. What I also suspect was happening was different doctors were giving different opinions and some were favouring their beloved treatment. For a clinical programmer, doing the research into the different options and seeing what trial data existed was an easy job. We know how to read trial results, know what are good numbers, whereas most people do not have a clue. This puts us at a considerable advantage. What we also have is a slightly cynical attitude to such data. We know that the data can be played with and explained away, so that we can be flexible when looking at numbers. To compare, someone I know was recently diagnosed with cancer. They were medically trained and got very fixed on the outcome from the medication, totally seeing the negative side of the results. That is something which rarely happened to me.

WE HAVE GOOD CONTACTS TO EXPERTS

I had multiple offers of contacts with Oncology experts, made by senior people in the industry. As I stated, I never used those, but I was very glad of the opportunity. It is wonderful to know that you have such resources available. It keeps you going and as I found out quite early on, your mental attitude keeps you going and plays a major part in recovering your health, so knowing I had this option was very uplisting.

WE ARE USED TO PUSHY DOCTORS

With several doctors giving advice it was clear that one doctor was pushing hard with his opinion and expected treatment. However, there were no conclusive results to justify the treatment. This felt like very familiar territory, how often have we seen a clinician push their favourite drug forward, despite conclusive evidence that it does not work?

Doctors also aim for the safest outcome. This might not always be the easiest in the long run and hence can provide conflicts with patients who are more risk oriented. It helps to be willing and able to question medical knowledge to choose your own path.

CONCLUSIONS

I took my relatives observations very seriously and knew that half task of regaining health was going to be in the head, rather than just physical. Clinical programmers are used to doing long tasks, which have fixed deadlines that cannot be moved. This perseverance is a key to coming through such a health situation, bearing up the pain whilst keeping a positive outlook. That is one of the most important things I found out about myself and my colleagues- perseverance, we all have this. It can be a lifesaver.

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