

Animal farm

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Are breast cancer patients being tricked or over-treated. Are the heavy dosage chemotherapy trials more terror than trial? **Brigid McLaughlin**, who herself signed up for a less aggressive trial, meets oncologist John Crown to lay bare the frustration (sometimes desperation) of breast cancer sufferers

I thought I never wanted to write about cancer or cancer treatment again but as I pushed a shopping trolley through Dunnes Stores last Wednesday, my stepdaughter Jane at my side throwing in cartons of coleslaw, I was thinking about the extraordinary fear that often lurks under the calm surface of life.

As a recovering cancer patient, searching for lamb and rice for that day's dinner, I was thinking about the controversial claims in the newspapers last week that the results of high-dosage chemotherapy on cancer survival rates are no better than regular chemotherapy. And I thought to myself, what are all these peculiar trials (I volunteered for one myself) that determine whether people live or die? And if they are mostly trials, it is clear our greatest experts still have no clue as to what works and what doesn't. what keeps us alive? And what has a fair chance of killing us?

In the year 2002, should people be receiving massive doses of chemical treatment when our cancer experts and medical purveyors are totally unaware of what the results will be? As I watched Jane lift pumpkins, I thought of her own hopes, future Halloweens, and mine. When she roared "Tick or treat?" to a smiling butcher, the irony of her words were not lost on me.

Are breast cancer patients being tricked? Or over-treated? Are those new findings trial or error, or trial and terror? Rather bleakly, and feeling much too sorry for myself, I told myself not to fret worrying about progress in cancer treatment, there wasn't any. On Wednesday I had a routine check-up with Professor Niall O'Higgins, head of cancer research and treatment in St. Vincent's Hospital. I waited three and a half-hours to see him. It was worth the wait.

Over the years, I've had as many public visits as private visits so it's fair to say I now know the difference. Private patients keep their gobs shut, public patients tell it as it is. There is, after all, plenty of time for talking. As the rains rapped the roof like a typewriter and the queues got bigger, I reflected on a few things that day: I wondered have we benefited and died from past mistakes in cancer trials?; could these trials exploits the desperate trauma of someone facing cancer for the first time?; should people think carefully before signing for a trial?; and, on a slightly different vein, I thought about the new generation of sad children playing around me who spend so much of their childhood in hospital waiting-rooms and chemo wards watching their mums quietly sniffing into tissues. Their sad, quick smiles. As we wait and wait, cancer rises like a shadow among us, the true enemy of happiness.

Two years ago, when I was battling chemotherapy, I frequently felt like I was an extra in the film *Animal Farm*, one of many battery-reared chickens queuing to see the anonymous Roosters, our oncologist, for two minutes of fate. Every single hour I spent in chemotherapy convinced me that this procedure was primitive. Beside me, there were two women suffering the effects of high-dose-chemotherapy. It was a shock to my system to learn that there was anything else but ordinary chemotherapy.

"High dose" is where a trial volunteer is taken in to hospital to stay for over a month at a time and blasted with toxic chemicals—at least 10 times the normal chemotherapy dosage—so much so that bone marrow has to be constantly replaced and white blood cells are wiped out on a regular basis. It was horrifying to watch. Horrifying to hear Dr John Crown tell them "there are no guarantees with this treatment, I'm afraid I can't give you prognosis". Now and again someone wanted to beat John up, including myself. Often I found John's attitude bumptious under pressure but then if I was seeing what he sees every day I'd be buying myself a shovel and casket in Woodies.

Writing about the experience in this paper, and the horrendously high mortality in Ireland, I received a couple of very disturbing, sad letters from two readers telling me that I had no conscience, that because of my article on the exhausting effects of chemo, their family members were refusing to have it. I was devastated by these letters and felt sorry for the families. Now, two years later, we know that in cases of high-dose chemotherapy, they were better off without it.

I went to see the man himself. According to Dr Crown, it's all good news for cancer patients from now on, we might feel like guinea pigs but we're getting the best practices from America. The trials have discovered that the benefits from aggressive treatment are no better than ordinary chemotherapy. "The result of this project," he says, "is the final nail in the coffin for high-dose chemotherapy for breast cancer. The good news is that future breast cancer patients are going to benefit from this study, one of the benefits is that ordinary chemo has got *better*. Nobody now is getting high-dose chemotherapy." Fatalities occurred from the complete devastation of the immune system and the resulting attacks of infection which shattered bodies could no longer resist. These trials were conducted until stopped 18 months ago.

"So it's congratulations and commiserations at the same time," I said wearily.

"Yes," he said. "When I received this award, [The Certificate of Merit from the European Society for Medical Oncology in recognition of outstanding scientific achievement] I dedicated the study to the women who signed consent for high-dose chemotherapy who knew there was a possibility that they might die," says Dr Crown. "Only five women died from the chemo itself," he said. To me, it's five too much. Undoubtedly, Doctor Crown has done fantastic work, a wily blend of spot-on research and hard-hitting facts. His study is technical. Complex. Probably brilliant.

But I'm thinking of the breast cancer patients not the jargon. I'm thinking of the sick mothers, daughters, sisters, not the trial statistics which cover us like tombstones. I'm thinking of the poor women pushing their trolleys with babies under five, young weak mothers who can barely pick up a packet of corn flakes, reeling as they are from the toxicity of "ordinary chemotherapy". Cancer patients will tell you that there is nothing "ordinary" about chemotherapy. And, personally, I'd say we don't know the half of what's going on and if we did we'd be sorely shocked. Who is to say that in ten years time a new trial will show that lower doses will disappear in favour of no dose. Judging by today's fogged-up mortality figures we are at crisis point.

I know from my own research that, despite the maze of pitch from drug companies, a confusing technospeak that Einstein might find challenging, we know sweet nothing about a cure for cancer.

"Sit down for a second, Brigid," said Doctor Crown solemnly as I was about to leave. "I just thought I'd tell you that the trials have been suspended by the Irish Medicines Board." I couldn't believe what I was hearing.

The IMB issued a statement stating that it had suspended the recruitment of new patients to all clinical trials being conducted at St Vincent's Private Hospital and oncology trials conducted at St Vincent's University Hospital in September following a report of a protocol violation.

The IMB confirmed that it has completed its inspection of the oncology clinical trials unit at St Vincent's Private and St Vincent's University Hospitals. A number of outstanding issues

need to be clarified before a final report can be prepared and presented to the Clinical Trial Sub-Committee of the IMB and subsequently the Board of the IMB for their consideration.

In the interim, the suspension of the recruitment of new patients put in place during September will remain. However, trial activities are continuing for patients who entered the trials prior to the suspension.

Under the Control of Clinical Trials Act 1987/1990, the IMB assesses applications for all clinical trials and licenses those trials that meet its approval specifications in terms of quality, safety and efficacy. The inspection encompassed all aspects of the conduct of clinical trials in accordance with the IMB's remit under the Act and International Guidelines on Good Clinical Practice.

Dr Crown also finds himself in a battle with the hospital. "The drugs used for my trials were supplied free by the drug companies, yet St Vincent's Private Hospital charged patients top rates for them. "When patients queried VHI and Bupa charges, Dr John Crown bravely blew the whistle. This is the statement issued last week from St Vincent's Private Hospital in connection with the matter. "In mid-September, the board of St Vincent's commissioned an independent (Price Waterhouse Coopers) audit of our procedures to establish how this matter of inappropriate charging for drugs came about. We have been in discussion with the VHI about the issue and have agreed that the report will be shared with them. We have also already started repaying money to the VHI.

"The review also examined the implications for the hospitals operations with regard to continued or future participation in clinical trials and studies, and is intended to ensure that the necessary systems are put in place. The report has just been completed and will now be shared with the VHI and the Irish Medicines Board."

"By the way, Brigid," Dr Crown said I was leaving, "the results of the trial that you have been on won't be available for another two or three years." Thanks be to God for that, I thought, as I ran out of the joint.

It's too early to say if treatments are any better or have improved in terms of survival rates but the "measurements" have improved. For example we now know that out of 700 women with breast cancer that were put on high-dosage chemotherapy in this high-dose trial for three years, 107 died. The question is, did the high treatment play a part in their deaths? To me, that is one horrible statistic. Is it success in "measurement" that is generating awards rather than treatment, or survival and cure? Who knows. At least the measurement has stopped high-dose trials for breast cancer. Now that must be good news.

Naturally, we should acclaim any advances in cancer treatment, I'm sure Dr John Crown deserves his award and has to be vindicated, but it does show ludicrous life is when we're talking about technicians and "measurement" of survivals and deaths rather than "cures". Surely the Stephen Hawkin's department of statistics should be dealing with that, not a top medi-brain like Dr Crown. In the meantime, I wish every patient, bandaged by dreams, the best. Now, night falls fast; after dodging fireworks and flying witches, I tuck Jane asleep. As I gulp a mouthful of red wine, I realise a fog still covers cancer trials and, unlike the blur of the vine, Irish cancer medicine gives us no such comfort, so thank God for a little dimness. I nod to the man above. Our fate is in His hands and His alone. He is bigger and brighter than the rest. But now, down here on this earth, I finally know who I am. I'm just a statistic, one of "the women" who has survived breast cancer. A live one.

PICTURE: **[BRIGID]**: 'Unlike the blur vine, Irish cancer medicine gives us no such comfort'
Photo: Brian Farrell]

PROBE INTO CLINICAL TRIALS AT PRIVATE DUBLIN HOSPITAL

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By Colin Kerr
[FrontPage]

All clinical trials have been suspended at St. Vincent's Private Hospital, Dublin, pending the outcome of an inspection on the safety and efficacy of these trials by the Irish Medicines Board (IMB). The VHI has also confirmed that it is carrying out its own investigation.

Irish medical times understands that the investigation was instituted following complaints that the VHI was being charged for free study drugs at the private hospital. One of the country's top oncologists, Dr John Crown, told IMT he had notified the IMB there had been protocol violations on three studies.

He said: "The protocol violations were strictly and exclusively related to billing practices followed by the finance department of the private hospital in relation to free study drugs." When it was confirmed to me that this problem had arisen, I immediately notified the IMB and requested an urgent good clinical practice audit of the three trials in question, and the audit found no evidence of any patient safety issues whatsoever," he said.

The VHI told IMT it was aware of the allegations and was carrying out its own investigation.

The IMB said a preliminary inspection on the safety and efficacy of clinical trials at St. Vincent's Private Hospital had taken place, and a more detailed inspection to look into all aspects of the clinical trials taking place there would begin on Tuesday.

"The IMB states that they have suspended the recruitment of new patients to all clinical trials presently being conducted at St. Vincent's Private Hospital. Under the Control of Clinical Trials Act 1987/1990, the IMB assesses applications for all clinical trials and licences those trials that meet its approval specifications in terms of quality, safety and efficacy," said the statement.

A spokesman for St. Vincent's Private Hospital said they looked forward to co-operating fully with the IMB in its investigations. They had already been in discussions with the VHI about this matter, he said, and they had agreed any money charged inappropriately would be repaid to the VHI.

"We are conducting a review of our own procedures to establish how this came about," he said.

PICTURE: [Dr. JOHN CROWN]