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How two Jehovah's Witnesses were paid millions to restrict WA blood transfusions

- **by: EXCLUSIVE**
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The national body charged with overseeing a safe blood supply to Australians says more evidence is required to support the use of PBM programs.
Source: Supplied

THE WA Department of Health has paid almost $4 million to two Jehovah's Witnesses, neither of whom is a medical doctor, to roll out a statewide program to cut blood transfusions to thousands of patients being treated in public hospitals.

The Sunday Times can reveal the two men, Axel Hofmann and Shannon Farmer – whose religion is vehemently opposed to blood transfusions – won the lucrative five-year contract in 2008, with an American associate, without having to bid for the job.

Axel Hoffman.
Source: Supplied

The contract was approved by the Health Department for exemption from the usual open-tender rules because, according to the department, the trio were the only ones with the skills to plan and implement a "patient blood management" (PBM) program in WA.

The aim of the WA PBM is to identify patients "at risk of transfusion" and implement a management plan aimed at "reducing or eliminating" the need for transfusions using donated blood. It also aims to reduce the potential risks to the patient and cut the costs associated with transfusion.

However the national body charged with overseeing a safe blood supply to Australians says more evidence is required to support the use of PBM programs and the WA Health Department has failed to provide conclusive data that confirm the program has proven health benefits across the whole patient population.

The Sunday Times can also reveal:

● Certain patients at Fremantle Hospital, where the PBM program was piloted, are restricted to one unit of blood at a time regardless of whether their doctor recommends more than one unit.

● Literature advocating the Fremantle PBM policy states the single unit policy is in accordance with national guidelines – but no such evidence-based recommendation exists;

● As an alternative to blood, patients are sometimes given commercial drugs made by pharmaceutical companies. Some of these drugs carry significant health risk warnings.

● Mr Hofmann and Mr Farmer declared they have been paid various fees by pharmaceutical companies that make the drugs used as substitutes for blood transfusions.

● The department says that from 2009 to 2013 the WA PBM program was responsible for savings of almost $16 million in blood costs, but has failed to produce detailed costings to clarify that figure.

The man who championed the introduction of PBM to WA was the former Chief Medical Officer, Dr Simon Towler, who has known Mr Farmer professionally since the early 1990s.

The PBM rollout was given the go-ahead by the Health Department after receiving presentations from Mr Farmer and Mr Hofmann in 2007.

The department told *The Sunday Times* the religion of the two men was "known to the Department's State Health Executive Forum prior to contracts being rewarded (sic)".

However, Dr Neale Fong, who was WA Director-General of Health and head of SHEF at the time, told *The Sunday Times* that he did not think he was told that the men were Jehovah's Witnesses.

"I don't believe so," he said. "You've surprised me by mentioning it. I think it should have been declared."

Shannon Farmer.
Source: Supplied

However, Dr Fong said it probably would not have made any difference to the decision.

"If they are just motivated out of their own religious background, well, that just goes to the motivation, but the issue should still be able to be adjudicated on its own rights," he said.

"But I think from an ethical point of view it would have been useful for them to declare it."

Dr Fong said Dr Towler was the sponsoring executive of the program, which meant he was responsible for the policy related to it and for making sure "all the ducks were lined up" and that it made sense.

Dr Fong said the PBM proposal had made sense in terms of health economics and he had been very pleased to support it.

He stressed that the key consideration for any initiative was the welfare of the patient.

"Patient safety is always the highest issue here," he said. "It's not savings or efficiencies, it certainly is always a case of patient safety, always."

When told that the consulting doctors' orders for blood were sometimes overridden at Fremantle Hospital, Dr Fong said, "I would have some concerns over that."

Dr Fong stood down as Director-General in January 2008, three months before the contract was awarded.

"God knows what happened to (PBM), I don't know," he said.

The contract was for the "Implementation of a System Wide Patient Blood Management Program to the Department of Health" – the first time in the world, it is claimed, that a PBM program has been applied across a whole taxpayer-funded health system.

According to the Health Department, PBM is now operating at Fremantle, Royal Perth, Sir Charles Gairdner and King Edward Memorial hospitals.

'Medicine and Economics'

The Sunday Times has established that the contract was awarded on April 10, 2008, through an Austrian entity called "Medicine and Economics" (M&E), which is owned by Mr Hofmann, a health economist who has a base there.

Under the contract, M&E was paid $3,901,703. The money was paid into a bank account in Austria, according to the Health Department.

It is not clear why the contract was awarded to German-born Mr Hofmann's Austrian business entity, since he does not appear to have had any previous experience in establishing and operating a PBM program. He does not have a degree in medicine but he has a Master's in economics and a PhD in health science.

Dr Simon Towler.
Source: Supplied

Mr Farmer, who has no tertiary qualifications, and a California-based associate, who also is not a medical doctor but has degrees in economics and health science, have been involved in implementing such hospital programs, even though on a much smaller scale than the statewide program in WA. Mr Farmer was the co-founder of a "bloodless" surgery program in 1990 at Fremantle's Kaleeya private hospital.

During the term of the M&E contract, it is also apparent that Mr Hofmann and Mr Farmer received payments as consultants or guest lecturers from the pharmaceutical companies that make the often expensive drugs used as substitutes for blood transfusions.

Mr Hofmann has declared payments or travel support for consulting or lecturing from at least 14 pharmaceutical companies. Mr Farmer has declared that he received lecturing or consulting payments or travel support from at least six pharmaceutical or related companies.

The Sunday Times has tried to contact both men without success.

Dr Towler, who has long been interested in alternatives to blood transfusion and has published articles on the subject in peer-reviewed journals, told *The Sunday Times* that he commissioned the strategy document for the WA PBM program.

> ***It was a completely legitimate project. We chose to engage people with substantial expertise in delivering hospital-based programs.***
> ***Dr Simon Towler***

"It was my idea," said Dr Towler, who is now the clinical co-lead at Fiona Stanley Hospital. "It was a completely legitimate project. We chose to engage people with substantial expertise in delivering hospital-based programs."

Dr Towler referred questions about the tender and terms of the contract to the department, but told *The Sunday Times*: "Through PBM, we have saved more than we spent on the project."

Chief Medical Officer Gary Geelhoed
Source: News Limited

Current Chief Medical Officer Gary Geelhoed said the M&E contract – which was awarded several years before he came into the job – had undergone due diligence and had been given a formal exemption under the tender rules.

"This concept was so new," Dr Geelhoed said. "They got selected because there was no one else around in Australia."

However, programs along the same lines had been operating in hospitals in the US and western Europe for years before the plan was put forward for the WA health system.

Asked why an Austrian entity was awarded the WA contract rather than tenders being sought from around the world, Dr Geelhoed said, "Well, I could not comment on that."

He said the five-year contract was not renewed last June 30 when it expired because the consultants had fulfilled their role, which was to spread the PBM concept across the health system, introduce the idea to clinicians and hospital staff, give lectures, produce written material, and provide a "blueprint" of how to implement the program.

"The outside consultants educated people. They got people onboard," he said.

Both Dr Towler and Dr Geelhoed argued strongly that they believed Mr Hofmann and Mr Farmer's religion was irrelevant to their getting the contract.

'Nothing Inappropriate'

Health Minister Kim Hames told *The Sunday Times* he was aware of the circumstances surrounding the PBM contract because questions had been raised in 2012. The questions were raised by one of these reporters.

"After then reviewing the information on the program, I was fully satisfied with the way it was implemented," Dr Hames said.

WA Health Minister Kim Hames.
Source: News Limited

"I remain confident that there is nothing inappropriate about the nature of the contract or the program itself."

The program officially started in WA in July 2008, but the rollout of PBM across the whole hospital system was not announced until April 2011, with a brief media release quoting Dr Towler. There was no mention of the involvement of any external contractors.

The Sunday Times does not suggest that Dr Towler, who is not a Jehovah's Witness, obtained any financial benefit from the PBM contract or was motivated by any other factor other than a genuine belief in the project.

The WA PBM initiative has been promoted, at international doctors' conferences and in medical journals, as being a world leader.

However, there has been no mention that Jehovah's Witnesses, whose religion not only prohibits transfusions but also bans blood donation by members, have been key players driving the WA PBM project or that millions of dollars were spent on their services.

And the results of the introduction of PBM, in dollar terms or patient outcomes, have not been published in any of the WA Health Department's annual reports between 2008 and 2013.

There is not a single mention of it in the Health Department's 2012-13 annual report for the Metropolitan Health Service, which includes Fremantle Hospital.

Dr Geelhoed told *The Sunday Times*: "It's been a very successful program and saved a lot of money. The program pays for itself. I'm happy to say that."

In March, *The Sunday Times* asked Dr Hames whether he believed the $3.9 million M&E contract was "value for money" for WA taxpayers. The Minister has failed to respond.

MIXED DATA ON HEALTH IMPACT

Fremantle Hospital
Source: News Limited

The Patient Blood Management (PBM) program has resulted in improved patient outcomes such as fewer complications, reduced length of stay, fewer infections and reduced usage of red cell blood products, the WA Health Department claims.

The Sunday Times asked the Health Department on March 28 to provide the results of patient outcomes from more than five years of PBM initiatives in WA.

More than five weeks later, the department provided four graphs on superficial (skin) infection rates and hospital length of stay.

There was no rationale provided to show how superficial infection rates might be caused by blood transfusions.

According to the US Centers for Disease Control and Prevention and other medical establishments, superficial infections involve the skin only.

The four graphs showed data from 2008/9 to 2012/13 in selected patients.

Two graphs showed the superficial infection rates along with red cell transfusion rates in hip and knee replacement patients.

The graphs showed superficial infection rates generally went down as transfusion rates went down.

But both graphs showed superficial infection rates in one year went up as the red cell transfusion rate came down. In another year, superficial infection rates in knee replacements went down as transfusion rates went up.

The two other graphs supplied showed changes in length of stay in hip or knee replacement and heart surgery patients.

The graphs show that the length of stay was higher in patients who had a blood transfusion.

There were no data to show how blood transfusions directly affect length of stay, including whether patients who had a blood transfusion had a longer length of stay because they were sicker.

In all graphs, no actual patient numbers were given, only percentages, so it is unknown how many patients in these select groups were included in the statistics.

The department did not produce any results for "fewer complications" apart from the superficial infection rates.

The "reduced usage of red cell blood products" is not a patient outcome.

The department also did not provide any data on whether patients who were refused a blood transfusion or received a restricted amount of blood under the PBM program suffered any adverse effects or were readmitted to hospital.

The department said it would not be commenting further on the issue of the PBM program.

In an online medical journal article last year, the WA PBM team reported on the implementation of the PBM program from 2009 to 2011 at Fremantle Hospital, in which some requests by doctors for blood for their patients were refused and some patients were given restricted amounts of blood.

The only specific patient outcome reported for the three years was that in some patients undergoing knee surgery, the average length of stay in hospital decreased from six to just under five days.

The main outcome reported was that there was a decreased number of blood transfusions.

There were no reported results on whether patients' health benefited or was adversely affected by not being given a blood transfusion, or by being restricted to a single unit of blood at a time.

The article's conclusion was that the PBM program "likely improved outcomes" by reducing patient exposure to donated blood transfusions.

What is Patient Blood Management?

- Patient Blood Management is defined as identifying patients "at risk" of transfusion and providing a management plan aimed at "reducing or eliminating the need for allogeneic transfusion". Allogeneic blood is donated blood. The rationale is that this will reduce "inherent risks, inventory pressures and the escalating costs associated with transfusion".
- PBM developed from "bloodless" medicine and surgery which originated in the US in mainly community hospitals that were seeking a marketing advantage in the competitive American health market by specifically catering for Jehovah's Witnesses, whose religion forbids blood transfusions.

- PBM may be used in patients undergoing surgery as well as patients with non-surgical disorders such as anaemia, or blood cancers such as leukaemia and lymphoma, or other medical disorders. PBM has also been used in patients with massive bleeding.
- It is used in patients who have elective surgery, are admitted to hospital for acute health problems (rapid onset and/or a short duration), or who are in intensive care.
- National Australian guidelines are being developed for use of PBM in newborn babies, children and pregnant women.
- PBM strategies to minimise or avoid blood transfusions include the use of manufactured pharmaceutical drugs, such as intravenous iron and ESAs (erythropoiesis-stimulating agents), and the use of equipment such as the cell salvage machine which collects, filters and washes the patient's own blood, which is later reinfused. Another PBM strategy is acute normovolemic hemodilution, in which the patient's blood is withdrawn and the lost volume is replaced with "volume expanders". The withdrawn whole blood is then transfused back during or after the procedure.
- The drugs used in place of blood transfusions, the cell salvage machine and the acute normovolemic hemodilution technique carry risks of adverse events. Two of the drugs, including the ESAs, and one of the volume expanders have a Black Box warning, which means they are potentially fatal.
- The National Blood Authority (NBA) in its newly released guidelines on Patient Blood Management in surgical patients says more clinical evidence is required to support the use of PBM programs. The NBA said it could only make a grade C recommendation concerning the adoption of PBM programs. A Grade C recommendation, which is the third lowest of four levels, means the evidence provides some support for the recommendation but care should be taken in its application.

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