AMS

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Transcript of Interview with Dr. Tim Craft, AMS

(You can find the audio interview here: Part 1 & Part 2)

Speaker key

IV Interviewer
TC Tim Craft

IV Well, I have with me Tim Craft, who is the Deputy Medical Director at the Royal United Hospital in Bath. Tim is also an anaesthetist, and when he's not actually working in the theatre, he's...or directing the hospital, he's also Director of a company called AMS, which is essentially a medical devices company specialising anaesthesia. Tim, I wonder if you could explain a little bit about how a practising clinician has got into running a company selling medical devices?

TC Well, I think the answer, you know, sort of in short, has to be, by accident. It was certainly never a plan to set off down that route, but it came about, really, because of the changes in clinical practice that were happening, largely in the late 1990s, in particular in the United Kingdom, and that's around a means of administering anaesthesia directly into people's veins. It's called Total Intravenous Anaesthesia, or TIVA. Historically, I think, everybody thinks anaesthesia is to do with breathing gases, but a technique became available, which was to anaesthetise people exclusively intravenously. Lots of clinical advantages, both as a practising clinician, but also from a patient's point of view from having that style of anaesthetic. So that started to take off. We became very interested in it here in Bath. I think we like to think ourselves as being quite a forward thinking department, and so quite early on got involved in practising Total Intravenous Anaesthesia. What worried me, though, and I think others around me, was that the way in which we were connecting the pumps that pumped the drugs into people's veins were just inherently dangerous, and what we were doing was opening drawers in our anaesthetic rooms, and operating theatres and picking bits of kit and cobbling them together in a very kind of Heath Robinson fashion, which did not include what, to my mind, were essential safety features. So that led me, really, to sit down and say, well, okay, if what's out there isn't fit for purpose in our view, and yet this is a technique that we want to continue to develop, what do we need to do to make it safe?

IV And had you done anything like this before? It's a big jump from saying, it doesn't work, to, I can do something about it.

TC Well, have I done anything like this before? Have I criticised things? Yes. Yes, for sure, you know [laughing].

IV [Laughs].

TC That's...I guess doctors do that a lot, don't they? Criticise things they see around them. Had I done anything in terms of doing something about it? No. But I just felt that it wasn't right to portray ourselves as a very forward-thinking, safe department, and continue to practice this particular style of anaesthesia unsafely.

IV So how did the process work? Did you start tinkering at home with rubber tubing and so on? How did it all happen?

TC No, I had no idea what we were going to end up with in terms of end product, and didn't really pay much attention, to be honest, to think about what it might look like. We started off by sitting down with a blank piece of paper, getting a few guys together after work. It cost me a round of beers and several packets of crisps.

IV [Laughs].

TC We just put it all down on a piece of paper. What are the features of a drug delivery system that we would want to see included to make it safe from the patient's point of view? And so that's a very sort of bottom up driven design, really, inasmuch as it was a design. It was just a list of key features that the connector systems had to have.

IV But this wasn't just you, this was you and several colleagues, so this was a shared sort of input on, if we could design a perfect one, this is what it would be like?

TC Yes. Yeah. But they were colleagues who, like me, had become interested in TIVA, and who, like me, were concerned about the ways we were connecting the drug infusions to patients, with intravenous fluids and different pumps and drugs, so what were we going to list as being the essential features of a connector system to improve patient safety? So that's how we started with it.

IV So we're in the pub. We've got a sketch of all the things that should be there. How do we move from that to a prototype and then to something in production?

TC I think that's probably where I did sort of pull myself away from the rest of the guys, because, okay, that was a list, and it cost me a few beers, but nobody was particularly interested in trying to do something about it. And I suppose that was the difference between, and remains, I think, a difference between me and most of my colleagues. What I then did was get together with a friend, who in fact I knew from school. Not from my school, but from my children's school. He has children, or had children at the same schools. His background is finance, corporate finance. He's not a clinician at all. And I said to him, I've got an idea for developing an intravenous connector system, which could become commercially viable; do you fancy helping me sort this out? And he didn't take very long to say yes. So having done that, we then had to go about taking this list of ideal characteristics to a medical plastics manufacturer and say, we need to turn this into something that's palpable. Something that people can hold, and look at, and test, and say, is this the shape of the connector system we need? So that was our next step.

IV And how did you handle the intellectual property question? Because even at that early stage, once you start showing it to somebody, there's a big question mark.

UM Do you want [unclear] sit [unclear]?

IV [Inaudible].

TC Um...

IV How did you handle the intellectual property question?

TC By a bit of a hit and miss approach, but by approaching a patent attorney in the city where we are at the moment, and saying to him, we've got this idea. What about it? And we then set off in search of a medical plastics manufacturer with a lot of agreements under our arms, which were to do with confidentiality and disclosure agreements. But again, quite accidental. You know, I didn't sit down and think, oh, before I have a conversation I need to make sure I've got a disclosure agreement. We had those conversations with disclosure agreements in hand, but it, more by luck than judgement.

IV And then this manufacturer was able to make up some prototypes? Did you then test them back on your colleagues? The ones who had been in the pub?

TC Yeah. We did. It took us quite a while, actually, to find a suitable manufacturer. I suppose I used my clinical knowledge of who makes what in the United Kingdom to pick a list of likely candidates, who we then went off and had meetings with them, and talked to them about their abilities and their interest in the project, before we got anywhere near designing what would become ultimately the connector system.

IV And getting permission to use this, or to test this in hospital, that must have been an issue as well?

TC Yes. I think it is very difficult and I think you, what you have to do is take, is have a leap of faith, and go a long way down the track towards producing a fully assured and fully certified product to then use on patients. I don't...I can't see a way of getting there with something that, you know, that might be useful in the future, but let's have a go. It just doesn't work like that. So you can bench test prototypes in that form, but when you get to the stage where you actually want to use it clinically, I don't see an alternative to being a fully-fledged, CE marked product. You simply can't use even components or connector systems that aren't in the patient's body. You can't use them without being adequately CE marked, and of course insured.

IV As a patient or potential patient I'm quite glad about that [laughing].

TC Yes.

IV But then, clearly, one of the issues, once you've tested this out and it does work, and it is certified, is getting your colleagues in the profession to adopt it. Can you talk a bit about how that process worked?

TC Well, I think it was relatively easy because we were dealing with a fairly blank canvas. There wasn't a good alternative available. So it wasn't particularly difficult to say to people, if you are using TIVA, then we believe that this product that we've now designed as a consequence of this wish list that we put together is the right way to go. I think that might have been difficult if we were facing a lot of competitive products. You know, why choose this one over that one? But we started off locally, so in my own hospital, with a CE marked and assured product, and testing it here, really.
Costing the company that we then established, which by now was a limited company, with public insurance policies and, you know, patent attorney fees and something that was costing quite a bit of money to establish, and then giving product free, to people to test. So that's what we did here in this hospital.

IV And that was then, and roughly when are we talking about when you say [unclear]?

TC I guess the late 1990s.

IV Okay. And we're now in 2008. Can you tell me a little bit about the journey since then?

TC Well, a lot's happened. Firstly, the first manufacturing company that we formed an allegiance with have gone. We ended up with some prototypes and we ended up from them producing products that were good, and they did establish a reasonable marketplace in the UK in particular, had a lot of loyalty to the products, and once we got products into hospital and it was being used, people didn't move away from the product. The problem was that they weren't big enough to move up a gear with us in the direction that we wanted to go. An example of that would be the injection mould process. We'd had some tools made, which were good, and we own the patent to a particular connector, or a particular component on the connector system, but the product that was coming out at the end of it could have been better, in terms of quality in particular. This is a piece of plastic hub into which pipes are glued. And if the plastic hub isn't completely smooth inside, then when the plastic tube is glued in it, you know, drugs and fluids would leak. And we were having little issues like this all the time. So to move the company and the business up a gear, we really needed to move to a different manufacturer.

This happened at the same time as we were approached by probably the world's leading manufacturer of pumps themselves, and their pump sale staff were saying, we keep coming across this connector system in the United Kingdom, please can we have it to put in our pumps? We'd initially said, no, you can't. We said no more than once, because we felt we were going to lose control of our business, and we couldn't innovate in a way that we wanted to. This is a global company that's owed at an American base, and we saw all kinds of problems working with a, you know, supertanker that couldn't change direction very quickly at all. In the end though, they persisted, and they said, we want, we definitely want to work with your connector systems, and we want access to your technology, to your patented technology; what can we do to satisfy you on this? And so we helped that relationship by moving to a new OEM manufacturer, who was a manufacturer approved by this major pump manufacturer, so we did that very much jointly.

They're based overseas, so they weren't an easy company for us to find, being based in the UK, so we used the pump manufacturer's knowledge of factories and manufacturers to find a company that's owned and based in France, but whose factories are not in France at all, chiefly because they take advantage of cheaper labour costs in other countries. So the products are now made in Morocco, of all places, by a French owned company. Still our own labelling, still our own badge, still our own design, but a company whose quality assurance processes are actually much sharper than the company in the UK that we were originally working with.

IV And in terms of innovation, you started off with this user-driven…this frustration of what was there. That gave you your first product or product range. How have you continued that innovative line?

TC I think in two ways, firstly. You're right. We came out first of all with the first product and part of the innovation there was to turn this product into a product

range, to hear end users say, this is good for this application, but on the other application we need something a bit different. So by listening to end users, we were able to grow that particular product range.

I think we then developed a reputation for being a company that make products that end users specifically want, and can have some influence over, in terms of [inaudible] and so people started to come to us and say, what if we just did that? Or, what about this? And so constantly now, we get a fairly regular trickle of emails and telephone calls from people who say, I've got an idea. What about it? Most of them have not resulted in new products, but I think we're willing to listen. We've got a philosophy that says we'll meet anybody at least once. So whether we subsequently go on to have further meetings…

I think what's, in terms of growing the company, what's particularly satisfying is that we have, again, fairly frequent phone calls from people who want to take our products for distribution in different countries, or, in one case recently, actually want to buy the whole company. So it's quite pleasing to be able to sit back and have people phone you and say, can we do some work together?

IV So it sounds like you've built a very successful business, and in the process learned how to be finance, manufacturing, patent protection, a lot of other stuff, but if you were looking back now, to the 1990s, what lessons have you learned? What innovation management lessons in particular? Things you might not do the same way again?

TC Well, I think of the two of us, the two directors that own the business, I'm probably the one that tends to be more pessimistic about what we're doing…

IV [Laughs].

TC …than my financially based colleague. And I think I should have had more confidence at the outset that the idea was a good idea and that it would produce a commercially viable product range at the end. And I was always, especially at the beginning, I was always very nervous about the fact that we were sinking a lot of personal money into developing a business, and I think from my point of view, with, you know, pessimistic concerns about whether this was ever going to be worthwhile, there were several years of product design and development before we got anywhere near something we could produce clinically. And quite often you'd think, is it worth persevering? So I think the first thing was to have some confidence about what we were doing.

I think the second thing is not to have fallen into the various relationships that I have done almost by luck, and to have a much clearer view of what you needed to do, in terms of a pathway towards developing a product. And I suspect that for both of us, my co-director included, would actually have meant taking professional help, seeking professional help from people who could have said to us, this is how you go from concept to commercially viable product.

IV Yeah. Yes, it does seem as if there's a number of complementary knowledge sets, and you either bump into them by accident…

TC Yes.

IV ...or, if you can, find professionals who can guide you or act in that role themselves.

TC Yes. I think I read a lot, and I continue to read a lot about the whole process of product design and innovation and have learned a lot from what I've read. I think I learned more from the relationships that we've developed with the patent attorneys within the companies that manufacture. In particular, if I go right back to the beginning, when we set off with our wish list on a sheet of paper, and found our way to what became our first manufacturing partner, I spent a whole day in a room that I'll never forget, surrounded by people that knew everything about medical plastics, about the components that they're made of, about the way they're sterilised and about the way you glue them together, about their shelf life, but who knew nothing about their ultimate application. That's what we brought to the party was an understanding of what they would ultimately be used for. So taking that list of desirable characteristics into that room, meant that at the end of the day we came out with sketches of what the end product would look like, and frankly, it's not radically different from what that very first sketch said to us. So for me, that was a real sort of light switch moment [unclear] the light bulb going on.

IV I think this fits very much in the Eric Von Hippel model of user-led innovation. Do you feel now, after a long time being doing this that you would be confident to advise one of your colleagues, perhaps in a different area in the hospital, who had also got a bright idea, perhaps was frustrated? Do you think now you could help him or her move forward with their idea?

TC I think I could. I think the amount of help that I could offer would be fairly limited though. I think my help might consist of, seek some professional help fairly early on. I'm interested in ideas, and I'm interested in turning things into commercially viable ideas. I still get a buzz out of that. So I would be quite interested to talk to people about their ideas, but I think there's a limit on how far I could take them down that path.

IV I wondered if we could broaden the conversation briefly? You also, apart from running a very successful business, continuing your innovating interests, and, on the side, acting as an Anaesthetist, and a Medical Director, but, leaving that to side, the NHS, the National Health Service, faces huge challenges and clearly innovation is part of their sort of strap line, their slogan. It needs innovation in all sorts of directions, in products, processes, systems; any thoughts about the challenges and any recipes for success, or recommendations you might want to comment on?

TC To agree with you straightaway that the NHS definitely needs to continue to innovate. I think it does innovate, but I think it needs to continue to innovate. I think what we've talked about so far is innovation at a fairly basic level, actually. It's innovation, which results in a palpable end product. If I'm going to be rude about my own products, it's innovation that results in a widget. For me, that's kind of first base in terms of what innovation's about. I think what the Health Service needs is innovation, which produces not just an end product that's patentable [?], but actually changing culture. So innovation in the way we think, innovation in the way we behave, innovation in the way we deliver care. I think if I talk to doctor colleagues in particular, when I talk to them about innovation, they imagine something shiny, metallic, that fixes somebody's hip, or possibly a drug. But innovation, in the eyes of a clinician has a very hard endpoint. I think what the Health Service needs is much

softer innovation that is about cultural shift, and a change in which we manage our processes as much as anything else.

IV And the obvious corollary to that, what are the things that might be stopping that happening?

TC Oh, the inevitable inertia that a huge organisation like the National Health Service lives with. Some of the inertia I think is healthy. I don't think you want your Health Service jumping on every bandwagon that goes passing by. So I think there is some health in inertia, but I would balance that by saying we do have to keep improving and keep innovating and keep making things better. So we can't just stand and hold our current ground. We've got to keep things moving forward.

I think an example of where I've used [inaudible] has been to say to colleagues that I think they could be forgiven for thinking, in the present climate in particular, that it's difficult to introduce new treatments or new methods of looking after sick people. I think colleagues may feel that litigation, that assurance, the processes that are designed to assure patients and organisations actually are there to clamp down on improvement, moving forward. I disagree with that. I think we have got to continue to improve and innovate. And so I've had a continuing dialogue with colleagues about that. I don't want to work in a hospital that doesn't innovate. I'm lucky; I work in a hospital that does innovate. And again, I don't just mean in terms of the production of end product. But an example would be, I said to my surgical colleagues, that I want you [sounds of door squeaking open] to continue to introduce new operations and to discuss them [unclear, sounds of door squeaking closed], but I want you to do so in a way that's assured and safe. And so I've helped them design a process, which is nothing more than an algorithm, which takes them through steps for how to introduce a new operation to this hospital. So it has to do with whether...what the indications are for this operation, what the training needs for you as a surgeon are, before you can start this operation, what the training needs for your team are, before they can start to assist you, in this operation, what the patient's needs are, so what you tell the patient what their needs are in terms of understanding what the process of the new operation is, what the reasons for having it done is, and how they consent for that. And then finally, what the business case for this new operation is. And I do put that last. I think it's important that the National Health Service is not a charity. Clearly it's not. It's important that we do make business cases for all the new treatments that we want to introduce. [Phone ringing]. But for me that's very much at the bottom of the stand.

TI So, that was seen by surgical colleagues as being actually a helpful thing, because it now meant that they could introduce new surgical procedures, and in a way that assured them that they were safe doing it, it assured their patients that they were safe doing it, and actually assured the hospital that they were safe doing it as well. This plan came about a couple of years ago because, and this is quite a tragic story, because a young girl who was born here in the early 2000s, ... and like her older brother before her, and like her younger brother subsequently, was born with a hereditary condition of her bloodstream called spherocytosis, and that means that her red blood cells instead of being shaped like nice doughnuts with a big dimple in the middle, are spheres, and the spleen says, ah these aren't good blood cells, these aren't normal blood cells, I'll take them out of the circulation, break them up and recycle the components. So, that's what the spleen does. So, the spleen is constantly breaking down all these red blood cells that are the wrong shape. So, what happens

to patients with spherocytosis is that they become anaemic because the spleen is commonly about the red blood cells and the spleen becomes pretty large. So, the proposed treatment is that the patient has their spleen removed, nothing more than that. This girl's elder brother had had this procedure done already, had his spleen out, and this girl herself was then referred to – in fact not to this hospital, not to surgeons in this hospital, but to a specialist paediatric hospital to have her spleen out. What the surgeon said was, ah instead of giving her a big incision right down her abdomen to get her spleen out, we're going to do this operation microscopically with telescope ports. And so we will mobilise the spleen with telescope ports and she won't have a big scar, she will have a much better cosmetic result, she won't be in hospital as long as she would be if she had an open operation, so it would be better all round. The problem is the spleen is so big that we're going to use a special instrument called a morcellator to chop the spleen up whilst it's still inside her, and then we can suck it out. So, this is all highly intended, well intended, this was a very good idea in my view. The problem is, they didn't tell the parents that this is what the plan was going to be, they didn't discuss the plan with the child herself, although she was fairly young at this stage anyway, but perhaps more concerningly, they didn't even discuss it with the rest of the theatre team, and it turned out that in the operating theatre nobody has used this particular instrument before. The surgeon himself had not used this particular instrument before. The operation was underway, the patient – the child was anaesthetised, and about an hour into the procedure as I understand it, she suffered a huge cardiac arrest and died on the operating table. The post mortem showed that she'd suffered internal organ damage, almost certainly as a consequence of the use of this particular instrument that nobody had used before.

So, for us that was clearly a tragic story, it's a story that we can all identify very closely with, not least because she was born here, she was a local patient, she was one of our patients. And so I use that story a lot in meetings around the hospital with a picture of this child with her mother's permission. Her mother knows that I talk very openly about it. We use a photograph of this child to talk about her experience, and then say, we want to introduce operations here in this hospital, but we don't want to do it like that, we want to introduce it in an assured way and make sure that everybody is safe.

IV That's a very powerful story. It also prompts me to think that we're moving then away from the sort of inspired sort of lone genius model of innovation, and much more towards what we see and what you've seen undoubtedly in your manufacturing side going on in other sectors, which is that you have to have a structured process, you have to have checks and balances, it has to be about taking risks, but they're calculated risks and they're worked through. Is there a sort of message here for the NHS to perhaps learn from out of its sector?

TI I think increasingly the NHS is being brave enough to seek health from outside its sector. A lot of my work in the National Health Service now is structured around patients' safety in its broader sense. So, not in particular with the care systems that we've talked about, but the patients safety in a very broad sense. My definition of patient safety doesn't end with whether or not you survive hospital admission, whether your operation is a success, it's a much broader definition and it's one that includes whether you as a patient feel safe, because if you don't feel safe, no matter how good the care obviously is, to my mind we're failing to deliver safe [?] patient care. I've noticed quite a big cultural shift again for people that work in the health service to understand. And so increasingly, there's quite a big focus at the moment on what traditionally might be considered to be customer care. So, simply talking to

patients and working with patients in quite a different way from the sort of paternalistic style of medicine of ten, 15 years ago, and we think in this hospital that one of the organisations that's particularly good at customer care is John Lewis. So, we're seeking help now from John Lewis and saying, you work with us to help us understand what we can do to work with our patients better. So, it's not changing treatments at all, the operations are the same, the treatments are the same, but we're working much more closely now, we're focusing on the patients needs as part of a shift in culture towards one that focuses more on customer care.

IV And it's a very interesting example, learning across from a retail sector into the health sector. I was struck by something I'd read in the paper recently about the Ferrari pit stop team working in Great Ormond Street, again same thing, what can you – what was interesting was, the Ferrari people said they learnt stuff as well, it's not a one way transfer.

TI No sure.

UM Tim that's been fabulous, thank you so much. One last question - since we're very near to Christmas time in having this interview, if I were the Christmas fairy, and I could grant you any wish you wanted, as a medical director, what would help improve innovation in your hospital?

TI I think it would be a change in mindset, a change in culture and a change in mindset that says, it's okay to have a go. I think we do have an awful lot of, what perhaps Rudi [?] called, analysis paralysis, whereby everybody takes any new idea, any change in the way we do something and they analyse it to death. And I think just once in a while somebody just needs to do something, be it small, bit size chunks, check and look back all the time, and ensure that your direction of travel is still appropriate, but you know, don't sit there inert, do something.

IV Sounds a good recipe. Tim, thank you very much for your time. TI

You're very welcome.