



## FiCTION Autumn Newsletter 2014

FiCTION (Filling in Children's Teeth: Indicated Or Not)

### FiCTION granted 12 month extension by HTA

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One of the biggest challenges that the FiCTION team has faced, in common with most other dental studies conducted in Primary Care, is recruitment. It has been very challenging for the dental practices involved in the study to find and recruit children of the correct age despite a supreme amount of effort being expended in screening and seeking out children who meet the inclusion criteria. 10,816 children, so far, have been screened and considered for the study across the UK and 7,022 children have attended. The consequence of this is that the recruitment period has been longer than originally planned. We are, in fact, still encouraging recruitment of children to the trial up until the end of this year although we are not too far off target.

Our recruitment total by the end of October was 1054, and we have predicted that we need to reach a target of 1113 by the end of December 2014. This means that we need to recruit a further 59 patients over the next 8 weeks. **This is achievable with a recruitment rate of 7 patients per week or, to put it another way, if every practice randomises one more patient to the trial.**

The funding body who support FiCTION have generously agreed to extend the end point of the trial to allow for all of the latest recruits to be followed up for the maximum time available and the end date of the study has formally changed to 31 December 2017.

Our continuing mission will be to try to retain all of the children that have been entered into the trial in order to be able to determine which of the three approaches to managing their caries works best.



### FiCTION Trial's Monty Duggal, Clinical Lead, Leeds Dental Institute Presidency of the EAPD



Photographed Monty Duggal, Clinical Lead, Leeds

Here's something that we picked up in the University of Leeds' Reporter about one of the Yorkshire FiCTION team, Professor Monty Duggal.... He recently completed his two years' presidency of the European Academy of Paediatric Dentistry (EAPD). *"It was a great honour to lead the Academy"* he says. *"Under my presidency it has grown into an extremely well-respected organisation, whose guidelines and opinions matter in policymaking regarding care of children's oral health in Europe. I increased the international profile of the EAPD in non-European countries by hosting the first Hermes seminar, which was a huge success, aimed at developing young researchers and offering them mentorship from within the Academy. During my tenure we signed an agreement with publishers Springer to produce the official journal of the Academy European Archives of Paediatric Dentistry."*

## A very warm FiCTION welcome to Claire Macdonald our new Senior Trial Manager



*Photographed Claire Macdonald*

Our former Senior Trial Manager, Chris Speed, moved on recently and we are delighted to announce his replacement, Claire Macdonald. So, to follow on with tradition, we interviewed Claire, and here's what she had to say.....

### **With regards to your background, what did/do you do as well as this role and what was it that brought you onto the trial?**

*I started working at the Leeds Clinical Trials Unit in 2006 and after a period working within the Newcastle Hospitals NHS Trust I started work at the Newcastle Clinical Trials Unit in 2009. Initially as an Assistant Trial Manager working the SPIRIT trials looking at treatments for Chronic Myeloid Leukaemia. I became a Trial Manager in October 2011 and worked both academic and pharmaceutical funded studies, including complex interventions, clinical trials of investigational medicinal products and advanced therapy investigation medicinal product studies. I started working as a Senior Trial Manager on the 1<sup>st</sup> October 2014 and in this role I will be working on a range of studies one of which is FiCTION.*

### **What are you looking forward to most on the trial?**

*FiCTION will be the first dental study I have worked on so I'm looking forward to learning more about studies in this field and working with all the teams involved in the UK.*

### **We're just in the phase of retention of the FiCTION children – what would be your top tips?**

*The importance of the participants ongoing involvement in the study should be highlighted at the first visit and positive reinforcement provided a subsequent visits.*

- *Using visit reminders and planners*
- *Calls to participants between visits*
- *Appreciation items to acknowledge the time and effort of participants*

### **What do you do outside of work to relax?**

*I enjoy spending time with my friends and family, also my beagle Archie.*

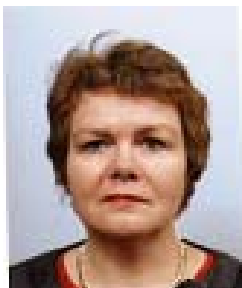
## Audit Hours information for Scottish practices

Under the new arrangements for clinical audit, participation in many dental research projects carried out by SDPBRN, universities and health boards will be eligible for up to five hours audit credit in each three year clinical audit cycle.

Dental research audit hours will be administered by SDPBRN via the NHS Education for Scotland (NES) Portal. Recognition of the impact of participating in research on the quality of dental care delivery is an exciting new development for dentistry in Scotland and SDPBRN are delighted to have been given the opportunity to help take this forward.

Further information can be found by accessing the links below. <http://www.sdpbrn.org.uk/index.aspx?o=3478>

## Welcome to Delwyn Sinclair—Scotland's new Clinical Lead Secretary



*Photographed Delwyn Sinclair*

Delwyn Sinclair has joined the FiCTION team based in Dundee all the way from New Zealand. Delwyn is working with the Scottish practices that are involved with FiCTION. We are sure you would like to join us in welcoming Delwyn to the FiCTION family. Here is what Delwyn had to say about moving to Dundee and starting her role within FiCTION;

*"I first became aware of the FiCTION trial 2 years ago when visiting Nicola Innes and Dafydd Evans at the University of Dundee to learn more about Hall crowns.*

*I work as a Dental Therapist in New Zealand for many years. I completed Grad. Dip in Business Studies, with focus on human resource management to support my role as mentor in clinical practice. Being part of the FiCTION team has given me an insight on some aspects related to dental research and after work in Dundee for 3 months, I have a greater appreciation of the complexities involved with such work. Outcomes of this research could determine how I treat the deciduous dentition in the future and I look forward to reviewing results when they become available."*

## Interview with two of the newest Scottish practices

We approached 2 sites that were recently brought on to the FiCTION Trial from Glasgow. Both sites have recruited fantastically well, and we wanted to get to know the secrets behind their success....

### Anita Belbin from Anita Belbin Dental Surgery—Glasgow

I have tried to be methodical about the screening log. I re screen patients every time they attend for an exam and have picked up patients who had no caries 6 months ago and now have early carious lesions. It can be difficult to remember but I have the birth dates of the age range jotted down so hopefully I don't miss anyone for screening.

If I find someone who meets the criteria I explain to parents that at present there are no clear guidelines about what to do with carious deciduous teeth and explain that the study sets out to do that.

I "sell" the study as a way children can become more engaged with the experience of going to the dentist and can build confidence and trust as well as providing preventive advice and care. ***I reassure the parents that I will not attempt to proceed with a treatment that is upsetting or painful for the child and explain that the questionnaires are also gauging how children respond to different treatments. I genuinely believe that being part of the study is beneficial to children with caries regardless of what treatment arm they are in, and this is what I tell my child patients and their parents.***

And parents seem pleased that time is being spent with their children and their children are becoming more confident about treatment as the study progresses.

As far as follow up is concerned, the children are returning, but sometimes the parents have forgotten that the child is part of the study and make a check up appointment for the whole family. This has happened a few times and we are trying to address this by altering the wording of the text we send to parents.

I think being part of the FiCTION team has been very positive for me and has improved my approach to treating child patients. I have got to know the children better and have had fun doing disclosing and brushing along with them.

### Raashi from Atlas Road Dental Surgery—Glasgow



Photographed Raashi Tinari (left) and Michaela McGhee (right)

**What is the secret to your success? How do you approach families and patients in the first instance?**

*After sending the letters in the post we allocate an extra 5/10 minutes for the child's appointment to discuss FiCTION. To help with randomising patients I have a link on my desk top which goes directly to the website and my password taped to the inside of my cupboard door to save time. As we all know the paperwork is the biggest bugbear involved for both us and the parents. We want things to run as quickly and efficiently as possible to make it not seem like such a chore to the parents taking part. **When discussing FiCTION I always call it a study and never a trial as I think the way you word things can either get parents interested or put them off immediately. The kids are fairly content and most are willing to take part as soon as they see the books!***

**Have you found it difficult to reach families when inviting patients to return for follow-up appointments?**

*I am lucky that most of my FiCTION patients are part of families who attend for appointments and just get booked back on for family check-ups and thus I haven't suffered from a lack of returns yet really.*

**Are families and patients interested to learn about the aims and objectives of FiCTION?**

*Understandably, parents can be very busy and sometimes by the time they have filled in the paperwork there isn't as much time to talk about the trial as we would like. That said, the children are always inquisitive and want to know why they are getting what they are getting and 'what colour the filling will be' etc.*

*We had one patient, however, whose mum I thought understood about his treatment when he was randomised to the biological arm and gave consent to the necessary treatment. At the next visit a stainless Hall crown was placed on one of the decayed teeth to repair it. Mum was upset with the how it looked and asked that the crown be removed. This was a big learning curve for me as a clinician, as at the time of randomisation I thought I was gaining informed consent, but Mum didn't know what a stainless steel crown was even though she nodded and agreed to the treatment. Now I show a crown to each and every parent and patient before cementing it in place to stop this happening again!*

*After that incident I now tell parents (probably far too much) about the study and discuss as clearly as I can all forms of treatment and what we try to achieve.*

**For families who do not consent, what are some of the main reasons?**

*One of the main reasons for me is a language barrier. I work in an area where, for a lot of my patients, English is not their first language and even trying to discuss the study via an interpreter is too difficult. Parents who think their children are being 'Guinea Pigs' don't want to consent and no matter how many times you tell them that you will always do what is in the best interest of their child they do not want to be associated with the study. We see lots of different patient groups in our area. Parents sometimes ask "It's just their baby teeth, why do we need to fill them? If they aren't in any pain won't they just fall out anyway?" or "If they've got holes can they not just get put to sleep and get them out like I did?" But it is our job as a dental team to help parents understand that dental care has changed for the better. We can now achieve so much more than we could in the past and children don't have to have the same dental experiences that their parents often did.*



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## What is FICTION?

The FICTION study (Filling Children's Teeth: Indicated or Not) is a multi-centre Randomised Controlled Trial (RCT) funded by the NIHR HTA, which aims to provide evidence on the clinical and cost-effectiveness of three treatment approaches to managing decay in the primary dentition.

The FICTION trial is addressing the Health Technology Assessment Programme's commissioning brief and the research question "What is the clinical and cost effectiveness of filling caries in primary teeth, compared to no treatment?" It will also compare an intermediate treatment strategy based on the biological (sealing-in) management of caries with no treatment and with fillings.

The study is a primary care-based multi-centre, three-arm, parallel group, patient-randomised controlled trial. Practitioners will recruit 1461 children, (3-7 years) with at least one primary molar tooth with decay into dentine. They will be randomised and treated according to one of 3 treatment approaches:

- conventional caries management with best practice prevention
- biological management of caries with best practice prevention
- best practice prevention alone
- followed up for at least three years

The joint Chief Investigators are based at the Universities of Dundee, Leeds and Newcastle – Professor Jan Clarkson (Dundee), Dr Nicola Innes (Dundee), Professor Gail Douglas (Leeds) and Professor Anne Maguire (Newcastle). The full trial team includes collaborators from Universities in Cardiff, Dundee, Glasgow, Leeds, Newcastle, Sheffield and both QMUL and KCL in London. This multi-disciplinary research team has been established to work alongside a UK-wide team of specialist paediatric and Primary Care dentists and members of their teams. This is to ensure that whilst the trial design and conduct is of the highest standard, it remains practical and pragmatic.