



FICTION Summer

The BIG Recruitment Drive

FICTION (Filling Children's Teeth: Indicated Or Not)

Summary of Progress

The FICTION Pilot Rehearsal Trial and Feasibility Study concluded in October 2011 and the Main Trial commenced on the 1st of January 2012. We are now 9 months into the patient recruitment phase which commenced in October last year and the study is due for completion in December 2016.

We currently have 45 dental practices in the FICTION trial and have recently recruited a few more to help us meet our target number of children; 3/4 of these practices have started recruiting; 451 patients have enrolled in FICTION so we are over 1/4 of the way there and the trial's recruitment pace has started to pick up. Some practices have already reached their target of 30 patients and are continuing to recruit as part of the competitive recruitment process.

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Photo supplied by
Tim Harker, a
FICTION GDP

Yorkshire Dental Practice' use of X-rays on Children

During the FICTION Pilot Rehearsal Trial the dental practices told us that taking radiographs in younger children was often problematic. To help with some of the common issues that the dentists told us about Kate Waldon in the Paediatric Department of Leeds Dental Institute produced a short video. This resource has been used during the training sessions to help the teams prepare for taking part in FICTION and is also being used to help train new dental staff within the FICTION practices so that they too can have a role in the trial in identifying potential recruits. Here's what Bhupinder Dawett from our Derbyshire Practice - Hafren House has to say about the value that x-rays have been playing in his practice:-

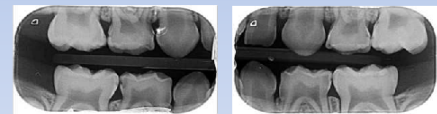
What a difference a ray makes...

Take the challenge below...

Where do you see caries in these primary molars?



What about now?



Remember:

1. Not all caries is visible clinically.
2. ICDAS charts should be completed based only on what is seen clinically; not radiographically.
3. Children who have no clinically visible caries but with lesions detectable radiographically **can be recruited to FICTION.**

"Taking bitewing radiographs in young children has been a hidden issue at our practice. We as clinicians knew about the FGDP guidelines, but in reality our audits showed a variation in practice. Prior to being involved in FICTION our dentists at the surgery rarely attempted to take bitewing radiographs in children under the age of 8 years. This behaviour I suspect was born out of difficulties that we as clinicians had experienced in the past, and the concerns that we have of irradiating young children. Since being part of FICTION we have now started to take bitewing radiographs on children at an earlier age after taking into account their caries risk status. This has been made easier now after acquiring a smaller sensor for our digital radiographic equipment.

What is apparent now is the fact that we have identified a number of dentinal carious lesions that we could not have detected and/or assessed adequately by vision alone. This has improved our diagnostic skills, helped with parent/patient communication, and helped identify patients that are eligible for recruitment into the FICTION. It seems that being part of a study like FICTION is beginning to change our practice for the better."



(left) Photo taken at a recent evening meeting in Glasgow being presented with their FICTION Certificates—far left photo—from left to right Alex Keightley (FICTION Team), Bozena Sporek from Possilpark, David Dunlop from Kilbirnie, Monica Taylor from Hampden, Elspeth Barker (FICTION Team)

(right) photo taken at a recent CPD meeting at Heckmondwike Dental Practice in Yorkshire being presented with their FICTION Certificate—from left to right Rob Montgomery, Amy Robbins, Gail Douglas (FICTION Team), Beverly Philpott (FICTION Team)

With over 250 members of the dental team now involved in FICTION across the UK, local meetings at the clinical centres give practices a chance to meet and discuss their experiences. Meetings provide a chance for the local Clinical Lead to update on the progress and direction of FICTION, for practices to share their stories of participating in FICTION, and for any training needs to be addressed. These meetings have been well received by practices, with feedback including: "I really enjoyed the meeting last night and especially discussions on caries detection technology. I would like to say how much I have valued the knowledgeable input of both you guys (the FICTION team). I am seeing great value in being part of a research experience such as FICTION. I feel I am learning a lot about conducting such project and maintaining it that will be applicable across the whole world of dentistry!! Thank you for coming down from Dundee to facilitate the experience." The frequency of these meetings will vary depending on local needs and the status of the trial, and CPD points are frequently available. Your local clinical centre will keep you informed of upcoming events in your area.

An interview with the FICTION Senior Trial Manager - Mr Chris Speed



How did you end up in the role of a Senior Trial Manager?

I really didn't know this is what I would end up doing. My background is in psychology and I started in the University as a Research Associate developing a disease specific Quality of Life questionnaire. I then moved to a project which was looking at lifestyle changes and the impact they have on health. So up until this point there was a direct link to psychology with the psychometrics and behaviour change. Newcastle set up a Trials Unit and my last project 'sat' within it, so I guess at this point I became a trial manager. Over the years since, the Unit has grown, the number of projects I've managed has increased and my role has moved from day to day responsibility for one or two trials to oversight of many trials and line management of the people who look after them. I tend to focus on paediatric trials and I'm hopeful the Unit will develop a reputation for carrying out research with this age group. I'm also responsible for the Unit's SOPs (Standard operating procedures). I still have an active role in developing assessment tools and patient reported outcomes, and I continue to look for *the* approach to recruitment and retention to trials.

Can you give us a brief update of the progress the trial has made since the last newsletter was published in May 2013?

Since our last newsletter we've had an additional 10 practices start recruitment for FICTION. The great thing about FICTION is the recruitment picture changes several times a day. If I tell the reader what the number of recruits now, by the time they put the newsletter down it'll likely be different. We're about a third of the way to hitting our target. I'm always grateful to each practice for every child they recruit and I know all the practice staff try very hard to support us.

Are there any common features or techniques between practices that are doing extremely well at recruiting patients to the trial?

FICTION is full of surprises. Historically in my primary care trials it is the biggest practices with the largest number of staff that tend to recruit the largest numbers of patients. In FICTION the first practice to hit their recruitment target was a single handed practice (Kingsway in Dundee) with a very dedicated GDP and Dental Nurse. I'd say that the common features in our most successful practices are 1) Team approach: everyone in the practice is involved in the process 2) Clear communication: to flag potentially eligible children so none slips through the net 3) Preparedness: all the paperwork is ready in advance, then once completed it is securely filed before coming back to Newcastle.

You attended an evening meeting in London on 27.06.13, what do you think are the main benefits of the FiCTION evening meetings?

Having been to a couple of Ferranti's London meetings I can say without doubt that a major benefit of attending is the standard of his catering. Seriously though, I attend as many of these evening meetings in the regions as I can and I think they are possibly one of the best support activities we offer in the trial. They are a chance for neighbouring practices to come together and share their problems, solutions, issues and successes. As you know FiCTION is spread all over the UK and the Clinical Leads meet regularly so these meetings are a great way of sharing experiences from other regions as well as locally. I've seen some really supportive gestures between practices such as offers of help to run patient searches. It is so good to see the goodwill there is for FiCTION to succeed but also from practices to see one another succeed.

How crucial is the role of the support staff within FiCTION practices?

In many ways the support staff are the most crucial team in FiCTION. Unless they coordinate and conduct the initial search and mail out to families we wouldn't ever get FiCTION started in the practice. They are responsible for getting the foundations laid so the clinical staff can deliver the interventions. As clinical trials require a keen eye for detail and generate lots of paperwork we know that the people who really get to grips with this are the support staff in the practice. As I said earlier, FiCTION is a whole practice trial, this is one of the reasons that we present support staff with certificates to acknowledge that without their contribution the practice would not have had the FiCTION success it has had.

In your role as Senior Trial Manager, what makes FiCTION such an exciting project to be a part of?

Without sounding too dramatic, FiCTION is a game changer. The evidence that FiCTION gathers has the potential to change the way that caries is managed in children, locally, nationally and potentially internationally. When you think of it in those terms FiCTION can't fail to be anything other than exciting. Those that have heard me talk about the questionnaires we use will know that the other thing about FiCTION that I find really exciting is our attempt to include children in the data we collect. We really are interested in what every child who takes part in FiCTION feels. FiCTION is a study that really does put our kids first, we're carrying out our research with our children not on them.

What makes it worthwhile coming into work every day as a Trial Manager?

I think that with FiCTION it is possibly the knowledge that this is likely the most ambitious paediatric, primary care dentistry trial anyone could attempt to run. We're running it, it isn't easy but we're making it a success. We have a great team of PIs and Clinical Leads and support staff and despite setbacks and bureaucratic hurdles we're still a supportive, productive and friendly team. We've never lost our sense of humour.

Finally, what's the strangest thing that's ever happened in a trial that you have been involved in?

Now this one might be lost somewhat in the translation unless you're from the North East. On a very early project, I had to carry out telephone interviews with parents of children who I was working with in their preschool. I met one little boy who was very engaging and carried out all of his tasks without any fuss. He was very chatty and smiley; a child you would immediately warm to. During the interview with his mum she revealed that he was autistic. I made a note to come back to this later in the interview and check the details of his diagnosis etc. It was a real shock as he didn't display any of the behaviours and traits we'd associate with the autistic spectrum. Mum, then went on to tell me that his sister was autistic too. This was very interesting to me as a researcher as there tends to be a much lower incidence in girls and here we had siblings with the same diagnosis. I then asked some open probing questions (as we're trained to do) only to realise that the children both did a lot of painting and drawing and were (in mum's view) very 'autistic' as they did lots of 'aut'.....

Recent and Upcoming Dissemination Events

FiCTION Evening Meetings:-

Cardiff - 30 April 2013
 Yorkshire - 1 July 2013 (Sheffield)
 Newcastle - 10 July 2013
 Dundee - 26 June 2013
 London - 27 June 2013

Data Monitoring and Ethics

Committee Meeting:- 8th July 2013

Trial Steering Committee Meeting:-
 22nd July 2013

FiCTION – on the web and VRE

The FiCTION Website is aimed at all trial participants <http://www.fictiontrial.info>. The VRE includes a list of all the questions we have been asked from dental practices since the trial started together with the answers. It also includes copies of all the documentation used on the trial. To enter the VRE you will need your login name and password supplied to you at the outset. All practices' patients' artwork has been received and will be judged shortly.

FiCTION Certificates

Framed Certificates, to include the practice name, have been produced and will be handed to each dental practice in due course through your local clinical centre.



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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 Dr Anne Maguire (Newcastle). The full trial team includes collaborators from the Universities of Cardiff, Dundee, Glasgow, Leeds, London, Newcastle and Sheffield. 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.