



# NIHR HTA INTERVAL Newsletter

Trial Office, Dundee, Dental Health Services Research Unit

**Welcome** to Issue 4 of the NIHR HTA INTERVAL Dental Recalls Trial Newsletter. We are pleased to announce that funding for Phase 2 (Full Trial) has been awarded, with a start date of 1 September 2011. This is good news and testament to the hard work of all those involved in Phase 1 (Feasibility Study). Sincere thanks are extended to our INTERVAL dentists & dental practice staff, UK Institutional Collaborators, members of the Trial Steering and Data, Ethics & Monitoring Committees and Research Network staff. We are indebted to recruited patients without whom the Trial would not be possible and to the NIHR HTA for their continued support.



We are now in a position to begin recruiting dentists for Phase 2. If any members of our readership are aware of dentists who might be interested in participating, the Trial Office would be very pleased to hear from you—Trial Office contact details can be found on page 4 of this newsletter.

Finally, Dr Fergus Daly recently moved to a new role working on the Scottish Health Research Register (a confidential index of residents of Scotland interested in contributing to health research as patients or healthy volunteers). We are very grateful to him for his commitment to seeing Phase 1 reach a successful conclusion and wish him every success for the future. A new Trial Manager will be sought and, in the interim, Dr Kulsam Ali has taken up the role of Trial Manager. Kulsam's contact details can also be found on page 4.

Professors Jan Clarkson & Nigel Pitts  
Joint Chief Investigators, INTERVAL Dental Recalls Trial

## Issue 4

## November 2011

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## Summary of Progress

- Phase 1 Findings:** The ways in which the Phase 1 findings have informed or suggested changed practices and procedures for Phase 2 are detailed on page 2.
- Phase 1 Final Report:** This Report was submitted to the NIHR HTA on 1 March 2011. It included statements from all four UK Chief Dental Officers (CDOs) endorsing the work of the INTERVAL Trial and recommending continuation to Phase 2 (comments made by the CDOs are detailed on page 2). Copies of the Phase 1 Final Report were circulated to members of our Trial Management & Trial Steering Committees.
- Phase 2 Grant Award:** An application for funding for Phase 2 was submitted to the NIHR HTA on 18 March 2011. The contract between the University of Dundee, the Department of Health and NIHR HTA was fully signed on 28 October 2011. The main follow-on trial will run from 1 September 2011 to 28 February 2017 (5.5 years). The total funding from the HTA is £2,670,030 amongst collaborating institutions: Aberdeen, Academic Centre for Dentistry Amsterdam, Birmingham, Cardiff, Dundee, Edinburgh, Leeds, Manchester, NHS Education for Scotland, Radboud University Nijmegen, St Andrews and University College London.
- Joint Award Agreements:** It is anticipated that the NIHR HTA will release the final 10% tranche of Phase 1 funding to the University of Dundee by early January 2012. Research and Innovation Services at the University of Dundee will contact collaborating institutions concerning Joint Award Agreements for Phase 2.
- Dentist Retention and Patient Recruitment:** Ten dentists were recruited and have been retained in Phase 1, although one has elected to postpone patient recruitment until Phase 2. Patient recruitment to date totals 313 (see page 4 for further information).
- Recruitment of Phase 2 Dentists:** Another 34 UK dentists will be recruited in Phase 2: 15 in Scotland, 10 in England (3 in Birmingham, 7 in Newcastle), 5 in Wales and 4 in Northern Ireland. See page 3 for further details.
- Research Network Meeting:** A valuable meeting was held on 4 August 2011 between the INTERVAL team and staff from each of the 4 UK Research Networks to plan dentist and patient recruitment and dentist remuneration during Phase 2. We are very grateful for the support and commitment pledged by Research Network staff.
- Committees:** The next meetings of the Trial Steering Committee, Trial Management Committee and Data Monitoring & Ethics Committee will now be convened as appropriate and those involved will be contacted.





## Summary of Phase 1 Findings:

The ways in which Phase 1 has informed or suggested changed practices & procedures for Phase 2 (Main Trial) were summarised in the Phase 1 Investigators' Final Report to the NIHR HTA and are listed below:

- ➔ Postgraduate Research Groups have provided a convenient and congenial environment for identifying and encouraging recruitment of dentists to INTERVAL. It is proposed to use them as a conduit to recruitment in Phase 2.
- ➔ Where more than one dentist per practice expresses an interest in recruiting patients to the Trial, this will continue to be accommodated in the interests of sharing and easing the burden of patient recruitment.
- ➔ The willingness of practices to alter local diary arrangements to suit the Trial (and in general by their engagement) is encouraging and the Trial Office will continue to work to gain this flexibility.
- ➔ The importance and value of the role of the Local Research Coordinator in encouraging dentist participation, assisting Trial progress, organising dentist remuneration and also in providing experience and opinions from another contributing institution cannot be exaggerated, and the building of strong personal and professional relationships with coordinators will continue.
- ➔ Length & design of Patient Questionnaire to be reviewed.
- ➔ Great importance is attached to good communications between the Trial Office and participating dentists to ensure dentist retention and smooth running.
- ➔ Phase 1 has illuminated the likely uptake to the 24 month recall interval across Scotland, England & Wales.



## Statements of Support for INTERVAL from UK Chief Dental Officers:

*"This trial addresses a crucial issue in relation to patient care and has the potential to affect dental policy significantly. It challenges a tradition of dental attendance at a time when we are anxious to make sure best use is made of resources and that quality of care is maintained. I am supportive of the study."*

Miss Margie Taylor, Chief Dental Officer, St Andrews House, Scottish Government

*"I support the proposed trial looking at dental recall intervals. Risk assessed recall intervals are key to our continuing policy initiatives. It is essential to have robust research and evidence on this topic to support future changes to the dental contract and this is currently lacking. Pilots of dental contract reform in England will be pursuing a risk based approach to delivery of care and recall. This research will improve our knowledge for development and implementation to the contract reforms."*

Mr Barry Cockcroft, Chief Dental Officer, Department of Health, England

*"I believe that this research project gives us the opportunity to obtain some solid evidence on the issue of recall systems and oral health. This evidence will be critical for future dental policy development in Wales."*

Dr David Thomas, Acting Chief Dental Officer, Llywodraeth Cynulliad Cymru, Welsh Assembly Government

*"I am writing to lend my support to the planned Interval Trial. I understand that Phase 1 is now completed and I would be keen that funding is made available to permit this project to move to full trial."*

*Currently in Northern Ireland, dental examinations are claimed under item of service and can be claimed every 6 months. We also have a 2-year registration period consistent with the maximum recall period recommended in NICE Clinical Guidance 19. In future we plan to introduce a new health service dental contract which is a blended system of weighted capitation and a reduced range of item of service. It is proposed that dental examinations will be subsumed into the weighted capitation element of the contract. It will be important that we can advise the profession and patients on the appropriate recall period and thus very important that we have robust evidence to support such guidance."*

*I am therefore pleased to see that Professor Clarkson and Professor Pitts are planning to undertake research in the area of dental recalls as it is an area where evidence is currently sparse. From a public health policy and health economics perspective, I believe this to be an important project and wish to declare my full support."*

Mr Donncha O'Carolan, Chief Dental Officer, Department of Health, Social Services and Public Safety, Northern Ireland



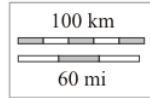


## Issue 4

### Dentist Recruitment Sites:

Ten dentists were recruited during Phase 1 in sites throughout the UK, although one has elected to delay patient recruitment until Phase 2. Another 34 UK dentists will be recruited during Phase 2: 15 in Scotland, 10 in England (3 in Birmingham and 7 in Newcastle), 5 in Wales and 4 in Northern Ireland. If any of our readers are aware of any dentists who may be interested in participating in the Trial, please contact the Trial Office (contact details are on page 4). Briefings are provided by the Trial Office at the dental practice, training is given on determining risk-based dental recall intervals via an online package (CPD points are awarded) and Good Clinical Practice training is also provided.

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#### Phase 1 Recruitment Sites

Locations on the map indicated with blue marker pins show where INTERVAL dentists have been recruited.

#### Phase 2 Recruitment Sites

In Phase 2, a further 34 dentists are to be recruited in the UK as follows:



**Scotland:**  
Additional  
15 Dentists



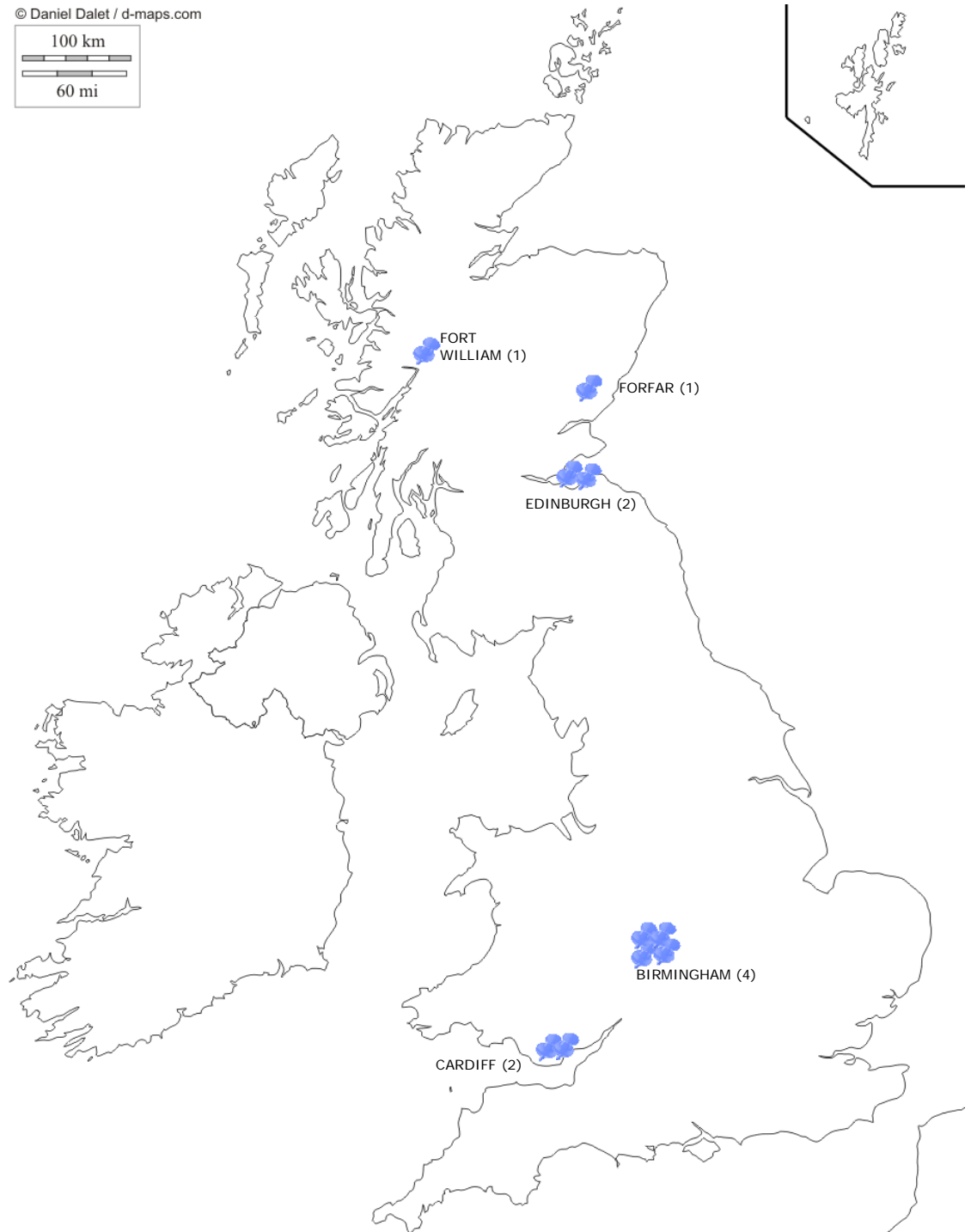
**England:**  
Additional  
10 Dentists



**Wales:**  
Additional  
5 Dentists

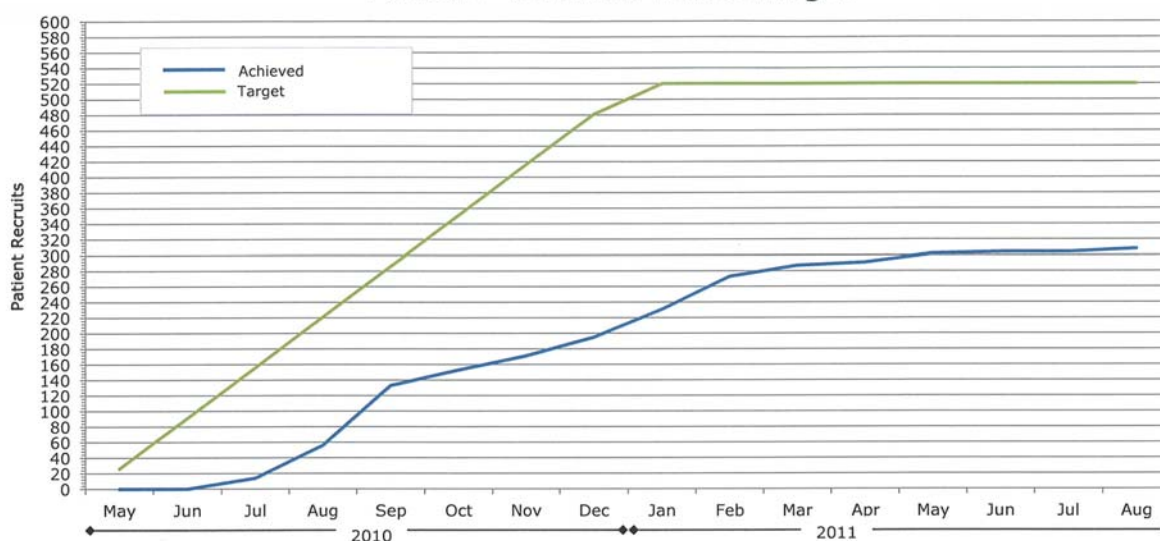


**Northern  
Ireland:**  
4 Dentists



## Patient Recruitment: Phase 1 May 2010 - August 2011

**INTERVAL Patient Recruitment  
Phase 1 - Achieved versus Target**



## Patient Recruitment: Update



Two of the four participating dentists in Scotland have achieved their targets of 52 patients (60 in Forfar, 54 in Edinburgh). The Fort William dentist has almost reached the target with 47 patients recruited to date. Despite best efforts from the practice and local research network staff, the second Edinburgh practice has encountered difficulties due to poor levels of literacy among the patient base, giving rise to a disincentive to complete the patient questionnaire and participate in INTERVAL. This dentist will monitor the 9 patient recruits achieved.



One of the four dentists in Birmingham has achieved the target of 52 patients (60 in total). The remaining three dentists have recruited 27 patients, 24 patients and 19 patients.



One of the two Welsh dentists (both in Cardiff) has achieved 13 patient recruits to date. The other Welsh dentist has elected to postpone patient recruitment until Phase 2.

The varying levels of patient uptake experienced by INTERVAL dentists has provided a valuable insight into patient recruitment in different regions across the UK. To date, patient retention has been good with 5 patients officially withdrawing from INTERVAL. Uptake to the 24 month arm continues to be a source of interest with more English than Scottish patients being deemed eligible for this arm.

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