Funding primary care research in dentistry:
A good practice guide for researchers

This paper sets out some guidance aimed at researchers planning to undertake research in dental primary care, particularly in an NHS setting, though many of the principles might apply also to research in private practice if it is publicly funded.

1. Background

Our ability to improve oral health is dependent on the ability to implement findings from high quality research, conducted in an appropriate setting. The setting may vary, from the laboratory to the population, but clinical research of the highest quality will always be an essential part of the process.

The UK government has recognised this and has invested large amounts of resource into clinical research in recent years, particularly through the National Institute for Health Research (NIHR) with a budget running into billions of pounds.

In many areas of medicine, a link to primary care is important, but in dentistry it is particularly important, and challenging. A range of settings need to be used for clinical dental research, including specialised secondary care facilities, but research involving primary care patients in primary care settings is a critical component.

All research costs money and as the vast majority of health care in the UK takes place in the NHS, the NHS ends up picking up large “background” costs over and above the sorts of things paid for by a research grant. This will vary from place to place, with greater costs falling where the research takes place. In NHS organisations (Trusts, PCTs, Health Boards) where lots of research takes place, more resource will be consumed to underpin the research. For this reason the NHS (through NIHR) sends more research support money to research focussed trusts and organisations. This principle, of support and infrastructure money following the research projects and ultimately the research patients, is fundamental to understanding the modern world of clinical research.

This is all very well, but there has to be a way of determining what is happening where, and what merits support and what does not; there is no point propping up poor research at the cost of supporting excellence elsewhere. The way this works is that all “approved” studies (RCTs and other well designed studies) are recorded on the NIHR portfolio – this is the database of all clinical studies that the NIHR will support on behalf of the NHS. Studies on the portfolio will be supported by NHS organisations locally so getting on to the portfolio is critical. The portfolio is overseen by local organisations called Comprehensive Local Research Networks (CLRN) in England. The devolved nations have equivalent arrangements. The local
organisations handle the money that comes from the centre and researchers involved in clinical dental research are urged to make contact with them.

The reason for this arrangement is related to the need to be transparent about use of public funds, and also the need to be fair in the way that money is distributed so that good research is supported.

2. Paying for research: Who gives research grants?

Research usually needs money, and often a lot of it. Obtaining substantial research grants is difficult and the general tendency is for grants to get bigger and fewer, targeting units with the greatest experience and track record.

A range of bodies fund research projects (one off studies) and programmes (sets of studies). For many years the Research Councils (of which the most relevant to clinical disciplines is the Medical Research Council) have been seen as the most prestigious funders, using a state allocation of taxpayers’ money to support selected high quality research and researchers. More recently the National Institute for Health Research (NIHR) have also provided direct grants for clinical projects. The state will also fund research through government departments and agencies.

Charities are major funders too, from huge national charities such as the heart and cancer charities to small local charities. Industry is a major funder of medical and dental research; research and development investment is essential to the success of companies operating in the healthcare sector.

Finally, some research is self funded or done in the researchers’ own time or supported by donations. This includes much research undertaken by clinicians, whether in universities, hospitals or primary care practice. The difference between these projects and others is that they are unlikely to be large and they are also unlikely to have been reviewed prior to the research. Some research funded in this way can be excellent, but there is little quality control.

3. Is that all? Do research grants cover all of the costs?

Research grants do not cover the full cost of delivering a clinical project and most of this document is to give some guidance as to how to manage these other costs as you will be asked about them if you are hoping to do clinical research in an NHS and maybe even in a private setting.

There are a number of activities within a project, wherever it takes place, even if it is in a private practice, that are not accounted for, and that historically would have just been absorbed by the host organisation. In dentistry that might include the extra time a dentist spends filling out forms for example or the time a dental nurse spends explaining a project to a potential patient, or even the rolling costs that continue after a project has finished but where the care initiated as part of the project needs to be continued or where the local site is requested to contribute to audit or assessment of the completed research activity. The way the costs fall can be split into three types, and these reflect where the funds come from.
The following describes the three activity based sources of funding:

a. Research Grants

This is the money provided by the organisations described above and in a clinical dental study will cover the following:

- **Staff employed and contracted** specifically to manage and deliver the project in hand, this includes professional researchers (perhaps dental academics, statisticians, economists), administrators, trial managers and others. These are time limited posts with people employed specifically, or people’s time is “bought out” from their normal employer by the grant. This is usually the greatest component of any research grant.

- In some circumstances this will also include primary care dentists or DCPs IF they provide a dental intervention beyond what they normally would provide or if they collect additional clinical data directly.

- **Travel, consumables and other running costs of the project.**

- **Dentists’ time spent learning about the study and training for it**, including the following activities
  - attending an introductory meeting prior to agreeing whether or not to participate (practitioner recruitment). The sum is generally based on the dental guild rate.
  - Any trial specific general briefing session for participating dentists (not GCP and clinical training)
  - Time for participants to read a protocol and brief their practice teams (guild rate).
  - Specific training for standardising or learning a clinical technique specific to the project.
  - Time spent undertaking Good Clinical Practice (GCP) training where required.

- **Reimbursements of costs (any fee) to ensure the correct level of data protection is in place for practices**

- **POSSIBLY patients’ travel or other costs incurred in their participation or any charges relating to treatments received** (but see below)

b. Service Support Costs

The research grant does not meet a range of hidden costs. Within the NHS it is the NIHR that reimburses the additional costs to the NHS for hosting research but only if the project is on the portfolio. The NHS has an obligation to support studies on the portfolio, but no obligations for those which are not.

This is more complex and abstract to calculate than the funds required for the research grant. These are the additional patient care costs associated with the research, which would end once the research has stopped, even if the same patient care service continues to be provided. In England these costs are administered by the Comprehensive Local Research Networks (CLRNs).
The situation is a little different in the devolved nations, but the principles are the same. The sorts of costs included for a dental study are:

- **Extra patient tests**
  - For example a radiograph which is only required as part of the research (and which would not be required if rolled out)
  - Saliva tests for specific screening
- **Access to the clinical facilities of a practice where the dentist does not need to be involved.**
- **Extra NHS staff time** over and above what would normally happen in the practice, ward or trust facility, such as;
  - Screening the patient
  - Recruitment, consent and randomisation (if done by a member of the practice team)
  - Arranging and undertaking follow up appointments

Significant and time consuming **additional treatments**, over and above normal care (or variations of what would normally be provided), would usually be a research cost rather than a support cost. However, each intervention needs to be looked at individually. In the FICTION feasibility trial, funded by the HTA, children were randomised into one of three groups each requiring a different level of intervention (prevention only, filling or biological management, often using a stainless steel crown). All are legitimate and normal treatments in their way so there is no additional research cost, but there are the support costs of recruiting, consenting and reviewing the patients.

In the past these things would have just been absorbed and fitted in by the clinical team, but when many patients are involved the knock on effects in a practice could be very significant. In a primary care setting, a few minutes here or there collecting data can impact in overall activity. The NHS will pick up these costs for portfolio studies and reimburse the practices.

c. **Excess NHS treatment costs**

These are the most difficult to understand and also usually the least relevant to dentistry. Treatment Costs are the patient care costs which would continue to be incurred (by the NHS) after the research study itself has stopped. It represents the financial legacy of the work. It is the “per patient” difference (excess) between the new treatment regimen which needs to be continued once it is started, and the standard. Usually treatments being researched are more expensive than the standard treatment (but this is not always the case); thus excess treatment costs are usually (but not always) positive, or additional. So this may be more or may be less but takes an averaged approach. It is abstract in the sense that no money may change hands but it needs to be worked out up front so that everyone is aware of hidden costs.

This is really designed to manage (for example) very expensive drugs, which, once the treatment is started, would need to be provided beyond the end of a trial so does not particularly concern dentistry for the most part. An example
might be an Alzheimer’s drug which may need to be continued for years after a trial.

We strongly recommended that if you think you have some “excess treatment costs” that will run into the future that you take early advice about this from the speciality group or your CLRN.

However, there is an example from a dental trial (the INTERVAL trial which is investigating the optimum recall interval) where excess treatment costs had to be calculated. The following paragraph demonstrates the thinking that informed that calculation, and also illustrates the averaging process and broad simplification that is necessary in any such calculation.

The INTERVAL trial follows 2,288 recruited patients over 4 years of follow-up. The intervention resides entirely in varying the recall interval between check-ups and in itself costs nothing, but the costs are contained in the consequences for treatment. “Normal” care consists of two check-ups a year, costing £16 per patient per year (at £8 per patient per visit, this figure derived from NHS tariffs). On the trial, 43% of patients are allocated to the usual twice-yearly visit; 14% are allocated to 24M recall (one visit every two years or “1/2 a visit a year”; and 43% are allocated to risk-based recall, which might be anything from 3M recall (4 visits a year) to 24M recall. Moreover, risk-based check-ups are more expensive than the standard, at £28. Based on pilot data the average risk-based recall interval was 8 months (or “1.5 visits a year). In this way therefore our estimated average annual per patient costs were:

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43\% \times (2.0 \text{ visits} \times £8) + 14\% \times (0.5 \text{ visits} \times £8) + 43\% \times (1.5 \text{ visits} \times £25)
= £6.88 + £0.56 + £16.12
= £24
\]

The excess treatment cost is therefore the difference: £24 - £16 = £12.

There are cases where the DH may need to pick up or subvent these costs if they are large.

If you are unsure about this we would recommend contacting the R&D leads locally.

**d. How do I work these out?**

The advice above is based on experience of doing this within dental studies, and particularly some major trials. A template for working out costs has been set up and used for recent large trials in primary care and can be obtained through the oral and dental specialty group. It breaks down each activity based on the protocol and applies a cost, generally based on the BDA guild rate. We would suggest consulting with the local CLRN as well. For secondary care studies the CLRN will be quite experienced in helping calculate these.

4. **What about patient charges?**

Dentistry possesses an extra-complication because patients pay a direct charge, even in the NHS. For research involving children and young people up to the age of 18 there is no patient charge collected in the NHS so there is no particular challenge. For adults, most will pay a patient charge though
some are exempt on the basis of income. The methods of collection are different across the devolved nations but the underlying principles around research are the same. What follows is based on recent experience, and the decisions are not always clear cut but it should represent the decisions to date.

For charge paying adults, a number of scenarios present themselves given the methodology and design of the study:

- **Scenario 1**: It is ethically questionable whether a new and expensive treatment provided as part of a clinical trial of efficacy (or a treatment provided as a control) should result in a charge to a patient. In such a case the treatment should be provided free. For the purposes of documentation the patient should be recorded as exempt from charge.
  
  **Outcome**: No charge, the cost is a research cost (no current example)

- **Scenario 2**: There may be circumstances where the patient charge is actually an important economic determinant of outcome in a pragmatic trial. In these circumstances it may be important that the patient continues to pay the charge. This was the case in the INTERVAL trial where the intervention was not new, just timed differently.
  
  **Outcome**: Continue to charge as normal (Example: INTERVAL trial)

  - **Scenario 3**: A little more difficult to evaluate is what should happen where a treatment is to be provided anyway, but variations in technique or material are to be evaluated. In this case, despite the normality of the experience, the procedure has been varied and the patient probably randomised in some way as part of a trial, and a strong argument can still be made for not charging the patient. However, the economics may be critically important to outcome. There is no hard and fast rule here, it depends on the question.
  
  **Outcome**: Probably charge patient as normal BUT seek advice

- **Scenario 4**: Finally there is a situation where an otherwise normal procedure is to be provided in the normal way but the researcher wishes to ask some questions about the experience or investigate the value of, or the attitude to the treatment (and perhaps even to the cost). It may even be that dentists commonly undertake the procedure in different ways and the research seeks to capture the impact of this variation by observing or questioning the patient, but not as part of a trial (i.e. without randomisation).
  
  **Outcome**: Probably charge patient as normal BUT seek advice

This does not preclude the researcher from providing a financial incentive for participants to provide data (for example to take part in an interview or complete a questionnaire) if appropriate. Such incentive payments would be a research cost.
5. Paying NHS Support costs to practices – the practicalities

It is the clinical site that incurs the NHS support costs. In a secondary care setting this is sorted out between the CLRN and the Trust. For dentists in primary care these additional costs need to be returned to the practice in full to compensate for the costs incurred.

There are various possible approaches to doing this, but the one which has been used and appears to work is for the CLRN to pay the NHS support costs to the practices and the practices undertake the research as an addition to their normal activity, including buying in additional staff if this is deemed appropriate. Other approaches where NHS contract values are altered are discouraged as they are complex to administer.

In practical terms, 4 times per year counted patient traffic is calculated by the research team and the CLRN (England) or SPCRN (Scotland) or the equivalents in NI and Wales are invoiced on behalf of the practice and the money paid direct to the practice. So the trial management team look after the communication with the Research Networks who pay the practices direct. This has been the approach used in several recent studies.

There is another possibility which is that some dental practices are part funded by the CLRN to undertake research when it is commissioned – a funded research network. This has not happened in dentistry yet in the UK, but has for GP practices. This may be useful but is unlikely to completely solve the problem, as the number of practices is dependent on the aims of each research project. There are pilot schemes which provide lower levels of support in order that practices are “research ready” which should help to speed up recruitment of practices to individual studies.

6. Seeking help and advice

Seek early help with this from experienced administrators, delaying it will only cause stress!

There are a range of people who can help work out costs and who can advise on precedent. In England, an early port of call as a protocol is developed for research funding should be the local Comprehensive Local Research Network (CLRN). There are 25 of these around the country. In the devolved nations the arrangements are slightly different but there are equivalent organisations.

The Oral and Dental Speciality Group, part of the Comprehensive Research Network overseen by NIHR covers all of the UK and can put you in touch with those who have experience of similar dental trials or studies who can advise on some of the detail and pitfalls, or can direct you to central NIHR for advice to help you through this confusing world.