The Pharmacy Practice Research Trust

M&P Medicines & People
Turning Knowledge Into Know-How

Investigating the effectiveness of pharmacist intervention in:

1) The Management of Long Term Conditions

- Heart disease
- Diabetes
- Hypertension
- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Mental health

2) Public Health

- Obesity and weight management
- Vascular risk assessment & management
- Sexual health
- Alcohol misuse

3) The Treatment of Minor Ailments

1. Call for Research Proposals

The Pharmacy Practice Research Trust (PPRT) has £300,000 available to fund up to three projects within the three topics listed above and is inviting applicants to submit research proposal applications for consideration.

Although some evidence of the effectiveness of pharmacist intervention in these three areas exists, it tends to be exploratory in nature and relatively small scale. The PPRT would like to see systematic reviews of this evidence and the conduct of multi-site trials to further investigate pharmacist intervention in these areas.

Project proposals must specifically address the aspirations of the White Paper for pharmacy[1] in providing evidence in terms of patient outcomes and economic value of pharmacist intervention. In addition, the project must deliver on the key priorities identified in the PPRT's Strategic Direction for Pharmacy Practice Research[2]. In particular the research must:

- investigate pharmacist intervention in either:
  - The management of long term conditions
  - Public health
  - The treatment of minor ailments
- be multidisciplinary
- be multi-site (either across devolved administrations or distinct regions)
- measure patient clinical outcomes
- measure patient quality of life outcomes
- include a robust economic evaluation

The research areas should be aligned with recommendations arising from the PPRT's Strategic Direction for Pharmacy Practice Research. For example the project could centre on:

- Newly diagnosed patients with a long term condition
- Independent prescribing services (pharmacist led clinics)
- Medication concordance amongst people with a long term condition
- Transfer of care from secondary care to the community

2. Pharmacist intervention in the management of Long Term Conditions

The effective prevention, management and treatment of long term conditions (LTCs) are current health policy priorities throughout the UK. Over 15 million of the UK's population are currently diagnosed as having a LTC and 60% of those aged over 65 live with at least one LTC. Collectively, the treatment and care costs of LTCs account for 69% of the total NHS and social care spending in England[3], with the total cost of caring for long-term illness being estimated at £69 billion per year[4].

The effective management of LTCs presents an opportunity not only to improve people's clinical outcomes and quality of life but also to provide efficiency savings through such things as:

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1 Department of Health (2008), ‹Pharmacy in England: building on strengths, delivering the future›. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083815

2 PPRT (2009), 'Workshop participants and stakeholder recommendations for research priorities for pharmacy practice research'. Available at: http://www.pprt.org.uk/Documents/ResearchActivity/Workshop_Outcomes_0309.pdf

3 Bunt, L. & Harris, M. (2009), 'The human factor. How transforming healthcare to involve the public can save money and save lives'. NESTA, London

4 The King's Fund/Institute for Fiscal Studies (2009), 'How cold will it be? Prospects for NHS funding: 2011-17', The King's Fund, London

- reducing the poor use and wastage of medicines
- reducing medicine related hospital admissions
- optimising skill mix through the appropriate transfer of care from GPs to pharmacists

Pharmacists have been described as ideally placed to support patients with long-term needs through such things as medicines management, regular monitoring of conditions and advice on disease management and lifestyle[5].

In England, the Government wants to see pharmacists expand and improve the range of clinical services offered to people with LTCs[6]. In Wales, Pharmacy Development is one of eight 'Foundations for Change' and incorporates calls for pharmacy to address the need for supporting people with chronic conditions[7]. Likewise, in Scotland, the Chronic Medication Service is a core component of Scotland's 'Pharmaceutical Care Services Contract'[8], enabling a wider clinical role for community pharmacists in patient care and the management of LTCs.

Many new or additional services are already being delivered by community pharmacists and the Department of Health report that a substantial number of studies and their findings have strengthened the evidence base of effectiveness for community pharmacy based services. However, most of the evaluations of these services have been conducted abroad in settings that are likely to vary from those in the UK[9]. Furthermore, in light of the forecast reduction in NHS funding that is soon to be realised, evidence of both the clinical and cost effectiveness of community pharmacy based services is going to be a pre-requisite in order for them to be commissioned.

2.1 Medicines Management

One area in which pharmacists can and do play a significant role in managing LTCs is through patient centred medicines management. Medication concordance is a complex area both to understand and to influence. However, it is a crucial aspect of any medicines focused treatment plan. In 2003, the World Health Organization found growing evidence to suggest that increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments[10].

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5 Public Health Commission (2009). 'We're all in this together. Improving the long-term health of the nation'. Available at: http://www.publichealthcommission.co.uk/pdfs/AboutPHC/PHCReport+Summary.pdf

6 Department of Health (2008), 'Pharmacy in England: building on strengths, delivering the future'

7 RPSGB (2008) 'Pharmacy and Integrated Chronic Conditions Management a summary of published evidence and practice examples', Available at: http://www.rpsgb.org/wales/pdfs/pharmintccmanwales.pdf

8 Scottish Executive (2010), 'Establishing Effective Therapeutic partnerships – a generic framework to underpin the chronic medication service element of the community pharmacy contract'. Available at: http://www.scotland.gov.uk/Publications/2010/01/07144120/6

9 Department of Health (2008), 'Pharmacy in England: building on strengths, delivering the future'

10 Department of Health (2008) 'Pharmacy in England: building on strengths, delivering the future'

Medicines are the commonest form of treatment used in the health care system[11] with many of these medicines being prescribed for the treatment of LTCs – within Scotland it is estimated that about two thirds of all medicines prescribed are for the treatment of LTCs[12].

Prescribed medicines are not always used as safely as they could be or in a way which provides optimum benefit. There are many and varied reasons for this. The Department of Health have suggested that about half of all adults with LTCs do not take their medication as intended by the prescriber[13]. This means that the patient fails to get the benefits they should from the onset of treatment. At worst, the patient suffers poorer health outcomes and increased morbidity, and the medicines are wasted[14].

In addition to the problems associated with non-adherence and medicines wastage, many patients are taking multiple medicines with an associated increased risk of interactions and adverse effects. Self medication with over the counter and herbal medicines further increases these risks[15]. In fact the Department of Health asserts that 10% of admissions to hospitals may be due to older people's inability to cope with their medicines[16].

Sub-optimal or non-use of medication is one key area in which pharmacist intervention could provide benefits both in terms of health outcomes and financial savings. For example, the Department of Health states that one in twenty hospital admissions can be avoided with proper medicines use[17] and that the estimated current cost of unused or unwanted medicines exceeds £100 million annually[18].

There are many points at which pharmacist intervention is likely to assist in medicines management. The PPRT has highlighted as priorities, research which focuses on support for newly diagnosed patients with a LTC and research which focuses on patients undergoing transfer of care from secondary care to the community.

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11 RPSGB (2008) 'Pharmacy and Integrated Chronic Conditions Management a summary of published evidence and practice examples'

12 Scottish Executive (2002) 'The right medicine. A strategy for pharmaceutical care in Scotland'. Available at: http://www.scotland.gov.uk/Resource/Doc/158742/0043086.pdf

13 Department of Health (2005) 'Choosing health through pharmacy. A programme of pharmaceutical public health'. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4107494

14 Department of Health (2008) 'Pharmacy in England: building on strengths, delivering the future'

15 RPSGB (2008) 'Pharmacy and Integrated Chronic Conditions Management a summary of published evidence and practice examples'

16 Department of Health (2005) 'Choosing health through pharmacy. A programme of pharmaceutical public health'

17 Department of Health (2008) 'Pharmacy in England: building on strengths, delivering the future'

18 Department of Health (2005) 'Choosing health through pharmacy. A programme of pharmaceutical public health'

Research suggests that there is a strong need for support for people newly diagnosed with a LTC. Only 58% of primary care patients who were prescribed new medicines in 2006 said they were given enough information about side effects. Research conducted in 2004 examined 258 people aged over 75 who were beginning new medicines for a LTC. Many of these reported problems with taking their medications and several also became non-adherent even if they were adherent for the first 10 days to four weeks[19].

2.2 Strengthening the evidence base – the call for research proposals

The PPRT have identified that there are insufficient large scale trials that investigate the cost of service delivery and the clinical and quality of life outcomes of patients following pharmacist intervention in the management of LTCs[20].

The large number of small exploratory studies across the UK should now be built upon through a systematic review which leads to the development of an exploratory, multi-site trial which investigates a specific pharmacist intervention in the management of one of the LTCs identified as research priorities by the PPRT. These LTCs are:

- Heart disease
- Diabetes
- Hypertension
- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Mental health

Several key topics have been identified as areas for research. These include:

- The role of pharmacists in the care of newly diagnosed patients
- Transfer of care from secondary care to the community
- The impact on medicines management
- The impact of independent prescribers/pharmacist led clinics on the long term outcomes of patients.

3. Pharmacist intervention in Public Health

Community pharmacies are easily accessible with the latest information showing that 99% of the population – even those living in the most deprived areas – can get to a pharmacy within 20 minutes by car and 96% by walking or using public transport[21]. In addition, community pharmacists are often

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19 Department of Health (2008) ‘Pharmacy in England: building on strengths, delivering the future’

20 Pharmacy Practice Research Trust (2009) ‘A strategic direction for pharmacy practice research. Summary of recommendations’. Available at: http://www.pprt.org.uk/Documents/ResearchActivity/Summary%20of%20Recommendations.pdf

21 House of Lords Debate, 12th October 2009, ‘Pharmacies’. Available at: http://www.theyworkforyou.com/lords/?id=2009-10-12a.79.0

patients' first point of contact, and for some their only contact, with a healthcare professional. This creates a unique opportunity to improve the gateways for signposting, accessing and providing services and information on health and health issues to a broad spectrum of the population, including the most vulnerable and hard to reach[22].

Pharmacists are uniquely positioned to provide public health services to large numbers of the population and many pharmacies now offer vascular risk assessment and management programmes, heart disease management and prevention programmes, diabetes screening and management, weight management programmes and smoking cessation services[23].

Some services are both sufficiently well-researched at an international level, for example in smoking cessation, lipid management in the prevention of coronary heart disease, immunisation and emergency contraception, that recommendations for their widespread implementation in the UK can be made. Other services are less well researched and require more evaluation before an assessment of their effectiveness and suitability in a pharmacy setting can be determined[24].

The PPRT has determined that the existing evidence on pharmacist interventions which has arisen from these small scale studies should now be systematically reviewed and extended to large scale trials which incorporate an economic evaluation of the services. The areas they have identified as priorities are:

- Obesity and weight management
- Vascular risk assessment and management
- Sexual health
- Alcohol misuse

3.1 Obesity and weight management

Obesity has been described as one of the most significant public health issues of modern times, with 24% of the population being clinically obese and with direct and indirect costs to the NHS of £4.2 billion per year[25].

Obesity is associated with many chronic conditions including type II diabetes, coronary heart disease and some cancers. Although many policy interventions have been aimed at preventing childhood obesity, it is in

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22 Scottish Executive, (2002), 'The right medicine. A strategy for pharmaceutical care in Scotland'

23 House of Lords Debate, 12th October 2009, 'Pharmacies'

24 Anderson, C., Blenkinsopp, A., & Armstrong, M. (2003), 'The contribution of community pharmacy to improving the public's health. Report 1: Evidence from the peer reviewed literature 1990 – 2001'. PharmacyHealthLink & the RPSGB. Available at: http://www.pharmacyhealthlink.org.uk

25 Bunt, L & Harris, M (2009) 'The human factor. How transforming healthcare to involve the public can save money and save lives'. NESTA, London

adulthood that these associated health problems often present and it is adults who account for the majority of obesity-related financial costs[26].

In addition to weight management programmes that focus on lifestyle changes, licensed pharmaceuticals are also available for the treatment of obesity, both by prescription or as over the counter medicines. In clinical trials, these drugs have been shown to result in greater weight loss than interventions that focus solely on lifestyle changes. Importantly, they also have a positive impact on weight loss maintenance, which is notoriously difficult to achieve[27].

Because of their accessibility both to people deemed 'hard to reach' and to the wider population, pharmacists are well placed to offer weight management programmes which incorporate screening and signposting if needed and which may or may not include the use of pharmaceuticals. However, although there have been many initiatives and projects to tackle obesity, there is still a need for more research and action on effective and cost-effective prevention of weight gain in adult life as well as weight loss maintenance[28].

3.2 Vascular risk assessment & management

Vascular disease includes coronary heart disease, stroke, diabetes and kidney disease. It currently affects the lives of over 4 million people in England. It causes 36% of deaths (170,000 a year in England) and is responsible for a fifth of all hospital admissions. It is the largest single cause of long-term ill health and disability, impairing the quality of life for many people. The burden of these conditions falls disproportionately on people living in deprived circumstances and on particular ethnic groups, such as South Asians[29].

Pharmacists have the potential to offer accessible and convenient risk assessment and management services with the potential to reach those who are most at risk of developing vascular disease.

The expansion of screening services have been described as essential for picking up symptoms or risk factors early on and for preventing conditions

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26 Musingarimi, P. (2008) 'Obesity in the UK: A review and comparative analysis of policies within the devolved regions', ILC-UK. Available at http://www.ilcuk.org.uk/record.jsp?type=publication&ID=24

27 Sjostrom L, Rissanen A, Andersen T, Boldrin M, Golay A, Koppeschaar HPF, Krempf M (1998). Randomised placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. Lancet; 352: 167–172. Cited by Musingarimi, P. (2008)

28 Musingarimi, P, (2008) 'Obesity in the UK: A review and comparative analysis of policies within the devolved regions'

29 Department of Health (2008) 'Putting Prevention first. Vascular checks: risk assessment and management', Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_083823.pdf

from materialising or worsening[30], and there are many ways in which pharmacists can play a role in providing screening services. For example, In-Pharmacy testing can help in screening for risk factors, diagnosing disease and monitoring disease. Screening for the early diagnosis of a disease or for risk factors can help prevent illness and alert people to the relationship between potential disease and their lifestyle[31].

3.3 Sexual Health

Pharmacists have long provided sexual healthcare whether this be through the provision of contraception, including emergency hormonal contraception, the provision of information and advice on the prevention and treatment of sexually transmitted diseases (STDs), or through providing chlamydia screening services.

Current estimates indicate that 16 to 24 year olds visit community pharmacies seven times a year on average. The development of appropriate sexual health services for this group in pharmacies could significantly increase their access to confidential professional advice and testing; leading to higher rates of detection of sexually transmitted infections and improved self care[32].

Research is needed to determine what impact pharmacist intervention has on national figures for STDs, unplanned pregnancy and safe sexual behaviours.

3.4 Alcohol misuse

Alcohol causes major health problems with up to 150,000 hospital admissions and 15,000 to 22,000 deaths in the UK in 2003 being attributable to alcohol. Between 1991 and 2005, deaths directly attributed to alcohol almost doubled and more people die from alcohol-related causes than from breast cancer, cervical cancer and MRSA infection combined[33].

The health cost of alcohol misuse is estimated to be £2.7 billion annually[34]. In spite of this, the funding of alcohol services is a particular concern. In comparison with drug treatment services they receive limited investment significantly out of line with the scale of the problem with which they deal – only one in eighteen people get the help they need. Independent research confirms that the payback on investment in early intervention alcohol

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30 Department of Health (2009) 'High quality care for all: our journey so far'. Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_101674.pdf

31 Scottish Executive, (2002) 'The right medicine. A strategy for pharmaceutical care in Scotland'

32 Department of Health (2005) 'Choosing health through pharmacy. A programme of pharmaceutical public health'

33 Watson, M. et al (2008) 'Community pharmacy and alcohol-misuse services: a review of policy and practice'. RPSGB. Available at: http://www.rpsgb.org/pdfs/commpharmalcmisuseservices.pdf

34 Department of Health (2009) 'Signs for improvement – commissioning interventions to reduce alcohol related harm', available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_102813

treatment is significant (savings of £5 per £1 invested), and comparatively rapid (realisable in one year)[35].

There are few published studies of community pharmacy-based services for alcohol misuse. However, there is a larger body of evidence from other primary care settings showing the effectiveness of brief interventions, (such as screening, assessment, alcohol education, simple advice, counselling and monitoring), for alcohol misuse. There is also evidence of the effectiveness of community pharmacy-based services for smoking cessation and other health promotion and illness prevention measures. These could form a good basis for developing alcohol misuse services[36].

Pharmacy-based interventions for alcohol misuse should be further piloted and evaluated as gaps will need to be filled in order to provide a convincing case for the wider commissioning of community pharmacy-based alcohol misuse services. There is insufficient evidence about the impact of services and none about their acceptability to service uses[37].

3.5 Strengthening the evidence base – the call for research proposals

Pharmacists have the potential to make a substantial contribution to the improvement of public health. However, measuring the value of public health interventions in terms of patient outcomes and economic criteria is notoriously difficult. Despite this, various small scale studies have been undertaken to examine the role of pharmacist intervention in many areas of public health. These small scale studies should now be systematically reviewed and used to inform large-scale, multi-site trials which incorporate an analysis of patient outcomes and an economic evaluation of services. The areas identified as research priorities are:

- Obesity and weight management
- Vascular risk assessment and management
- Sexual health
- Alcohol misuse

4. Pharmacist intervention in the treatment of Minor Ailments

Incidents of minor ailments are high, with research studies indicating that 90% of adults suffer from a minor ailment within a two-week period and 94% within the last year[38]. Currently, pharmacists are well used by the general public in the treatment of minor ailments with 14% of people using pharmacies to treat

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35 Department of Health (2005) 'Choosing health through pharmacy. A programme of pharmaceutical public health'

36 Watson et al (2008) 'Community pharmacy and alcohol-misuse services: a review of policy and practice'

37 Watson et al (2008) 'Community pharmacy and alcohol-misuse services: a review of policy and practice'

38 Hughes, D, et al (2008) 'Investigating factors influencing user choices to visit either general practitioners or community pharmacists in the management of minor ailments – piloting a discrete choice experiment'. PPRT. Available at http://www.pprt.org.uk/Documents/Publications/Investigating_factors_influencing_user_choices.pdf

one-off common conditions, such as colds, coughs, aches and pains, and stomach problems[39].

Recent years have witnessed an explicit shift in health policy towards encouraging increased self-care in the treatment of minor ailments; efforts that have been broadly supported by the government, general practitioners, community pharmacists, pharmaceutical companies and consumers alike[40].

There is potential for considerable reduction in GP workload if users could be encouraged to seek assistance from pharmacists instead. This would have a considerable impact on costs. An Audit Commissioned report estimated that the NHS could potentially save £236m a year by encouraging people to self-medicate minor ailments using non-prescription medicines[41].

In spite of this, approximately 40 per cent of all GP appointments are for minor or self-limiting illnesses[42]. This equates to some 57 million GP consultations a year (200,000 consultations per day) involving minor ailment discussion, 90% of which (51.4 million) are for minor ailments alone, equating to over an hour a day for every GP.

4.1 Strengthening the evidence base – the call for research proposals

Currently, the evidence base for pharmacist led minor ailments services is inadequate. The PPRT has identified that there seems to be no collation of evidence of minor ailments schemes in the UK. Nor does there seem to be any identification of minor ailments on which pharmacists could have significant impact[43].

In order to develop a robust evidence base around the topic of pharmacist intervention in the treatment of minor ailments, the PPRT would like to see the following points addressed:

- A systematic review of published and non-published data
- Identification of ailments that appear to have the highest impact on the workload of high cost services (GPs, A&E)
- Evaluation of different models of delivery of care which compares both costs and patient outcomes

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39 Department of Health (2008) 'Pharmacy in England: building on strengths, delivering the future'

40 Hughes, D, et al (2008) 'Investigating factors influencing user choices to visit either general practitioners or community pharmacists in the management of minor ailments – piloting a discrete choice experiment'. PPRT. Available at http://www.pprt.org.uk/Documents/Publications/Investigating_factors_influencing_user_choices.pdf

41 Hughes, D, et al (2008) 'Investigating factors influencing user choices to visit either general practitioners or community pharmacists in the management of minor ailments – piloting a discrete choice experiment'

42 Department of Health (2009) 'High quality care for all: our journey so far'

43 PPRT (2009) 'Workshop participants and stakeholder recommendations for research priorities for pharmacy practice research'. Available at: http://www.pprt.org.uk/Documents/ResearchActivity/Workshop_Outcomes_0309.pdf

- Research into the triggers to seeking care for minor ailments from pharmacies
- Evaluation of pharmacists' consultation and diagnostic skills in these areas and their impact on patient outcomes

5. Key areas of research to be contained within submitted proposals

- Research proposals must focus on pharmacist intervention in either:
    - The management of long term conditions
    - Public health
    - The treatment of minor ailments

The Trust recognises that pharmacist intervention in these three topics presents a broad and diverse research area in which many questions can be proposed. Therefore the research areas which have been discussed here are neither exhaustive nor exclusive and applicants should not be restricted but must explain and defend their choice of focus for study.

- The project must be multi-site, either across devolved administrations or distinct regions.

- Multidisciplinary working underpins the delivery of many new healthcare initiatives. Indeed, central to recent developments in care are calls for the delivery of services collaboratively, particularly in the care of patients with long term conditions[44]. Outline project proposals must therefore incorporate a multidisciplinary element.

- One intention of funding this research is that it will provide sufficient evidence to use as leverage for larger funding applications. Applicants are therefore requested to provide information as to how they envisage building on this project and which funding bodies they are likely to approach.

- Projects must be aligned with recommendations arising from the Trust's Strategic Direction for Pharmacy Practice Research[45] for example by focusing on:
    - o Newly diagnosed patients with a LTC
    - o Independent prescribing services (pharmacist led clinics)
    - o Medication concordance amongst people with a LTC
    - o Transfer or care from secondary care to the community

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44 Department of Health (2007) ‹Our health, our care, our say – one year on: making it happen - the third sector Event report, actions and next steps› Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_075491

45 PPRT 2009 'Workshop participants and stakeholder recommendations for research priorities for pharmacy practice research'

5.1 Key Outcomes

All research proposals must clearly demonstrate how they will effectively:

- Measure patient clinical outcomes
- Measure patient quality of life outcomes
- Include a robust economic evaluation
- Provide sufficient evidence to use as leverage for larger funding applications to build on initial findings.

6. Criteria for determining which research proposals will be accepted for funding

- Focus on the issues identified in this call for outline project proposals
- Clear research questions; sound design and methodology to address these
- Analytical strategy likely to provide meaningful (and preferably generalisable) results from the data
- Integration with and contributing to existing knowledge and theory
- Evidence that the research team is able to carry the project through, with clear project management arrangements and realistic objectives and timings; evidence of a suitable research infrastructure with an appropriate mix and seniority of disciplinary expertise and track record.
- Demonstrate value for money and impact

Those submitting proposals are invited to consider the nature of expected research outputs and how these might be communicated to important policy, practice and education audiences in ways that are likely to enhance impact.

7. Submission process

The Trust would like to invite research proposals from multidisciplinary research teams.

The deadline for submission of outline project proposals is close of business on the 14th of May 2010.

Submissions will be reviewed by external expert reviewers and applicants will be notified if they have been shortlisted for interview by close of business on the 25th June 2010

Interviews will take place on 7th July

For more details regarding the work of the Pharmacy Practice Research Trust please visit - www.pprt.org.uk

Information on all aspects of this call for project proposals is available by contacting:

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