Invitation to Tender
Department of Health Policy Research Programme

Evaluation of Physiotherapist and Podiatrist Independent Prescribing, Mixing of Medicines and Prescribing of Controlled Drugs

Deadline for submissions: **1.00 pm on 23 July 2013**

**Introduction**

1. This document sets out the research needs for an evaluation of physiotherapist and podiatrist independent prescribing. This includes the specification for a core evaluation, with supplementary strands to be addressed if possible. Funds of up to £200k are available to fund this research.

**Aims of the evaluation**

2. The first independent prescribing programmes and conversion programmes for physiotherapist and podiatrist supplementary prescribers to become independent prescribers will commence from late 2013/early 2014. This is subject to amendments to legislation, NHS regulations and approval of education programmes by the Health and Care Professions Council.

3. These changes will encompass:
   - Independent prescribing of medicines;
   - Mixing of medicines prior to administration;
   - Prescribing from restricted lists of controlled drugs (relevant to each profession). This is subject to amendments to Home Office regulations.

4. The primary aims of the evaluation are to assess effectiveness and efficiency of these reforms, including innovation in service delivery and impact on patients.

**Background: extending prescribing**

5. The Department of Health (DH) Non-Medical Prescribing Programme was established to extend medicines responsibilities to professions other than doctors and dentists. The programme aims to:
   - Improve patient care without compromising patient safety;
   - Make it easier for patients to get the medicines they need;
   - Increase patient choice in accessing medicines;
   - Make better use of the skills of health professionals;
   - Contribute to more flexible team working across the NHS.
6. The scope of independent prescribing by nurses was expanded in 2006, and independent prescribing by pharmacists and optometrists was enabled in 2006 and 2009, respectively. Supplementary prescribing was extended to physiotherapists, podiatrists and radiographers in 2005.

7. A report on Allied Health Professions prescribing was published in 2009\(^1\) which assessed the evidence base in this area. This report recommended that independent prescribing by physiotherapists and podiatrists should be taken forward, as a high priority. An engagement exercise took place in 2010, with full public consultations in 2011\(^2\). Proposals were subsequently made to the Commission on Human Medicines (CHM) and the Advisory Council on Misuse of Drugs (ACMD).

8. On 24 July 2012, Ministers announced amendments to legislation to allow physiotherapists and podiatrists to independently prescribe medicines, mix medicines prior to administration and prescribe from restricted lists of controlled drugs (subject to amendments to Home Office regulations)\(^3\). A commitment to evaluate the cost and benefit assumptions was included in the policy Impact Assessments\(^4\). Confirmation that an evaluation was required was given by the CHM main council and the ACMD Technical Committee.

**Related policy research**

9. These extensions to prescribing have been informed by research, commissioned by the DH which include evaluations of:

- Extended formulary independent nurse prescribing, University of Southampton, 2005\(^5\).
- Nurse and pharmacist independent prescribing, University of Southampton and Keele University, 2011\(^6,7\).
- Supplementary prescribing (prescribing in partnership with a doctor) by nurses and pharmacists, Universities of Sheffield and Nottingham jointly, 2008\(^8\).

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\(^7\) Full report published by Southampton University - [http://eprints.soton.ac.uk/17584/](http://eprints.soton.ac.uk/17584/)


\(^10\) [http://www.shef.ac.uk/polopoly_fs/1.44164!/file/Supplementary_prescribing.pdf](http://www.shef.ac.uk/polopoly_fs/1.44164!/file/Supplementary_prescribing.pdf)
Evaluation of physiotherapist and podiatrist prescribing: objectives

10. It is essential that the evaluation should seek to identify innovative and effective practice in independent prescribing, and assess the impact of independent prescribing in terms of:

- Patient safety
- Costs
- Health outcomes
- Patient experiences
- Communication between prescribers and patients’ GPs

11. In addition, the evaluation should assess:

- Quality and effectiveness of the independent prescribing education programmes
- Relevance and appropriateness of prescribing activity
- Possible unintended consequences

12. Other areas which could also be included are:

- Comparing supplementary prescribing with existing medicines mechanisms
- Equality and diversity impact
- Impact on waiting times and other system performance measures
- Implications for service redesign
- Barriers to effective implementation
- Changing perceptions of scope of professional practice

Cost benefit assumptions

13. Full cost and benefit assumptions for this extension to prescribing practice have been published in policy Impact Assessments and Equality Analyses\(^9\). These include, but are not limited to:

Cost Impact

- The monetised cost is the cost of the educational programmes preparing physiotherapists and podiatrists to prescribe independently. This includes both the conversion courses required for a move from supplementary prescribing to independent prescribing; and programmes which enable individuals who currently have no prescribing annotation to achieve independent prescribing status. Costs will be incurred only by physiotherapists and podiatrists who fulfil programmes’

entry requirements, and who wish to undertake these programmes

- Time commitment from physiotherapists and podiatrists to attend education programmes and any back-fill costs
- Complexities of governance of the professions
- Supervision costs of designated medical practitioners (DMPs)

**Benefit Impact**

- Health benefit from timely treatment, reducing risk of acute conditions becoming long-term conditions (LTC)
- Reduction in GP requirement in terms of time required to prescribe medicines
- Reduced patient’s time away from work to attend GP practice to obtain a prescription
- Health benefit to patient from reduced prescriptions and improved medicines adherence
- Improved communication between GPs and Independent prescribers

**Other benefits include:**

- Improved patient care and safety thereby reducing A&E admissions
- Improved access to healthcare for all, especially in rural settings and for the elderly
- Overcoming barriers for supplementary prescribers, e.g. clinical management plans in short-term conditions
- Potential increase in self-referral to physiotherapists, reducing patient care pathway further, particularly in specialist services and for patients with any long term condition(s)

**Constraints and requirements**

14. The scope of this evaluation is England only, although costs and benefits assumptions in the published policy Impact Assessments are UK wide, given the amendments to legislation apply to the UK.

15. The evaluation should enable comparison between the policy Impact Assessments’ assumptions, which include both qualitative and quantitative assumptions. The evaluation of the policy should therefore include, where appropriate, both qualitative and quantitative methods.

**Research design**

16. Whilst it is vital the evaluation meets the aims set out above, methodologies are not stipulated. However it is likely that methods will include

- Reviewing existing relevant research;
- Review of relevant data sources from the NHS and elsewhere
- Clinical audit;
• Primary data collection from patients and service providers, via interviews and surveys;
• Case studies of patients at points in the relevant care pathways

17. It is expected that the research will cover the range of settings in which physiotherapists and podiatrists work, including primary, secondary and tertiary care settings. The research should also cover a range of geographical locations in England, e.g. urban, rural, inner city, and include a range of patient demographics (referring to the Equality Act 2010 and the policy Equality Analyses)\textsuperscript{10}.

18. Applicants will need to demonstrate how they will maximise participants’ (patients and providers) involvement whilst limiting the negative impact of the research requirements in terms of time and resources. Research proposals will need to demonstrate how they will include patients in both the design and execution of the evaluation.

19. In addition, due to the relatively small numbers of physiotherapist and podiatrist prescribers, the Department of Health is particularly interested in the research proposals’ plans for ensuring that participants’ anonymity is preserved, especially when comparisons are being made between supplementary and independent prescribing and between prescribing professions.

**Outputs and reporting arrangements**

20. A project advisory group including patients, clinical professionals, professional bodies, regulatory bodies, education providers and Department of Health policy and research staff will support the research process. This group will meet periodically over the lifetime of the research in order to provide overall project management, advice and support to the research team.

21. As the evaluation of this phase of the AHP Medicines project will take place after the closure of the project board and project delivery team, the evaluation specification task and finish group and project board members’ names and organisations are included in Appendix B and C respectively for reference.

22. Successful applicants should be prepared to review evaluation objectives in conjunction with the advisory group, and to share emerging findings on a confidential basis. The successful applicant will be expected to:

\textsuperscript{10} Department of Health (2011), Proposals to introduce independent prescribing by podiatrists
Department of Health (2011), Proposals to introduce independent prescribing by physiotherapists
- Provide regular feedback on progress;
- Produce timely reports to the project advisory group;
- Produce a progress report, as agreed with the project advisory group in timely fashion so as to inform implementation; and
- Produce a final report for sign off by the project advisory group

23. The research team will be expected to provide regular progress reports over the lifetime of the research and will be provided with a progress report template to complete at regular intervals. In addition to describing progress, these reports will allow researchers to indicate any significant changes to the agreed protocol, as well as setting down milestones for the next reporting period, giving an update on PPI and also any publications or other outputs. Information on emergent findings that can feed more immediately into policy development will be encouraged and should be made available as appropriate.

24. A final report on the research, with an accessible executive summary, will be required within one month following completion of the research. The report will be peer reviewed and circulated to policy makers in the Department of Health. Once the study is complete, a summary of the final report will be placed in the public domain, on the Department of Health Policy Research Programme website. This is where the outputs resulting from expenditure of public funds are made available for public scrutiny so it is important that the summary of the final report is easily accessible to the lay reader.

25. Research contractors are obliged to give at least 28 days notice before submission of any publication arising from research funded by the Department of Health Policy Research Programme. In this instance, ‘publication’ concerns any presentation, paper, press release, report or other output for public dissemination arising from a research project funded by the PRP. There is no time limit to this provision and research contractors remain under an obligation to provide notice even after the contract has ended. Publication of PRP-commissioned research is subject to prior consent of the Secretary of State, which will not be held unreasonably and cannot be withheld for more than three months from the time the publication is submitted.

26. Research contractors will be expected to work with nominated officials in DH and partner government departments. Key documents including for example research protocols, research instruments and reports must be provided to DH in draft form allowing sufficient time for review.

Dissemination

27. Applicants should consider the full range of potential audiences and describe how the research findings could be disseminated most effectively to ensure that the lessons from this research impact on policy and practice in the NHS and the Department of Health. This can include research summaries for audiences of patients, service providers, commissioners,
regulatory bodies, professional bodies, higher education institutions and practitioners. Key specific ‘customers’ include:

- The Commission on Human Medicines and the Advisory Council on the Misuse of Drugs, in terms of patient safety and confirmation of cost and benefit assumptions;
- Government Departments and associated organisations, to assess the policy impact and to inform related policy;
- Healthcare commissioners, requiring evidence to inform the commissioning of services which include independent prescribing;
- Providers: to inform service redesign options;
- Clinicians: to identify effective practice, supporting service redesign, and improvement of services for patients; and
- Higher Education Institutions, to underpin development of curricula.

28. Wider audiences will include:

- Relevant professional bodies, to inform communications with members, pre-registration curriculum development, and the development of post-registration learning and development opportunities;
- Local Education and Training Boards and Health Education England, to inform commissioning of education programmes, and local evaluation;
- Centre for Workforce Intelligence – so models of future healthcare workforce needs can take account of changing service models;
- Regulators including the Health and Care Professions Council, Care Quality Commission, and Monitor, from a patient safety perspective;
- Patient groups’ representatives; and
- Other clinical professionals and related academic audiences, to ensure awareness of advances in practice and to support multi-disciplinary working.

General comments about applications

29. The Policy Research Programme (PRP) is a national programme of research dedicated to providing an evidence base for policy-making through the Department of Health. It provides information to the Secretary of State for Health and Ministers directly and through policy directorates in the Department and covers all aspects of the Department’s policy-making activity.

30. Applications will be considered from other UK countries provided they address the priority areas in a way that is relevant to the needs of the Department of Health (England) and meet all other selection criteria.

31. Applicants are encouraged to submit multidisciplinary applications.
Information for applicants

32. The sections below provide standard information on different aspects of PRP funding and will contain details relevant to your application.

Governance issues

33. Day-to-day management of this research will be provided by the chief investigator. They and their employers should ensure that they identify, and are able to discharge effectively, their respective responsibilities under the Department of Health Research Governance Framework for Health and Social Care\(^\text{11}\), which sets out the broad principles of good research governance.

34. All successful research involving National Health Service (NHS) and social care users, carers, staff, data and/or premises must be approved by the appropriate research ethics committee (REC) or social care research ethics committee (SCREC). For further information on RECs, please visit the National Research Ethics Service website: [http://www.nres.nhs.uk/](http://www.nres.nhs.uk/).

35. The successful research team must adhere to the Data Protection Act (1998) and the Freedom of Information Act (2000). Effective security management, and ensuring personal information and assessment data are kept secure, will be essential. In particular:

- The research team shall, at all times, be responsible for ensuring that data (including data in any electronic format) are stored securely. The research team shall take appropriate measures to ensure the security of such data, and guard against unauthorised access thereto, disclosure thereof, or loss or destruction while in its custody.

- Personal data shall not be made available to anyone other than those employed directly on the project by the research team, to the extent that they need access to such information for the performance of their duties.

Risk management

36. Applicants should submit, as part of their full application, a summary explaining what they believe will be the key risks to delivering their research, and what contingencies they will put in place to deal with them. Please ensure this is detailed in the Management and Governance section of the full online application form.

37. A risk is defined as any factor which may delay, disrupt or prevent the full achievement of a project objective. All risks should be identified. The summary should include an assessment of each risk, together with a rating of the risks likelihood and its impact on a project objective (using a high, medium or low classification for both). The risk assessment should also identify appropriate actions that would reduce or eliminate each risk, or its impact.

38. Typical areas of risk for an evaluation study might include ethical approval, site variation in data gathering, staffing, resource constraints, technical constraints, data access and quality, timing, management and operational issues; however, please note this is not an exhaustive list.

Patient and public involvement (PPI)

39. The Policy Research Programme expects the active involvement of patients and the public (e.g. service users and carers) in the research that it supports when appropriate. However, the nature and extent of patient and public involvement (PPI) is likely to vary depending on the context of the study. Applicants should describe how the issue of PPI will be addressed throughout the research process. For example, this could include patient and public involvement in refining research questions, designing research instruments, advising on approaches to recruitment, assisting in the collection and analysis of data, participation or chairing advisory and steering groups, and in the dissemination of research findings.

40. Applicants are required to describe what active involvement is planned, how it will benefit the research and the rationale for their approach. PPI needs to be undertaken in a manner that acknowledges that some people may need additional support, or to acquire new knowledge or skills to enable them to become involved effectively (see INVOLVE publications for guides for researchers). Applicants should therefore provide information on arrangements for training and support. In addition, applicants should note that a budget line for the costs of PPI is included in the finance form. Where no PPI is proposed, a rationale for this decision must be given.

41. For further information and guidance about PPI, please visit the INVOLVE website: http://www.invo.org.uk/

Budget and timescale

42. The Department of Health expects the research to be delivered within a cost of £200,000. Costings can include up to 100% full economic costing (FEC) but should exclude output VAT. Applicants are advised that value for money is one of the key criteria that peer reviewers and commissioning panel members will assess applications against.

43. The research will be conducted over the period 2013/14 to 2015/16.
44. The duration of the proposed study should be as short as is consistent with a high quality study. In addition, applications will be favoured in which research can commence on, or soon after, issue of a contract. This is in order that the research can inform implementation, via progress reports and a final report, likely to be required midway in 2015.

45. Funding to the level stated will only be available if there are suitable high quality and relevant studies.

46. Notification of outcome is expected to be given by November 2013. All applications are expected to start as soon as possible and no later than within 6 months of funding being agreed.

Transparency

47. In line with the government’s transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at: http://transparency.number10.gov.uk/.

48. If you wish to view the standard terms and conditions of the Policy Research Programme contract, please go to: http://prp.dh.gov.uk/applying-for-prp-funding/

Application process

49. To access the research specification and application form, please visit the Policy Research Programme website at http://prp.dh.gov.uk

50. The PRP Central Commissioning Facility (CCF) runs an online application process and all applications must be submitted electronically. No applications will be accepted that are submitted by any means other than the online process. Deadlines for the submission of research applications occur at 1.00 pm on the day indicated and no applications can be accepted after this deadline. We strongly recommend that you submit your application on the day before.

51. Once the 1.00 pm deadline passes, the system shuts down automatically and CCF Programme Managers are unable to re-open it. If you are experiencing any technical difficulties submitting your application, please contact the CCF on 0208 843 8027 in good time, before 1.00 pm on a closing date

52. This is a single stage tender and a full application is required to be submitted online by 1.00 pm on 23 July 2013.

53. Applicants will be notified of the outcome of their application approximately 17 weeks after the submission date.
54. Applicants are expected, before submitting applications, to have discussed their applications with their own and any other body whose co-operation will be required in conducting the research. The declarations and signatures page must be printed off and signed by an administrative or finance officer for the host (contracting) institution to confirm that the financial details of the application are correct and that the host institution agrees to administer the award if made. This is the only part of the form required in hard copy.

55. The hard copy of the declaration and signatures page should be submitted within one week of the closing date to:

**PRP Commissioning Round 7**

**Evaluation of physiotherapist and podiatrist independent prescribing**

PRP CCF
Grange House
15 Church Street
Twickenham
Middlesex
TW1 3NL

56. The standard PRP application process:

57. In standard one stage commissioning, all full applications submitted to the PRP will be peer-reviewed by both stakeholder and independent academic referees. Wherever time permits, applicants will be given one week to respond to the peer reviewers’ comments.

58. Full applications, peer reviewers’ comments and any responses to those comments will then be considered by the Commissioning Panel, which is comprised of independent experts (possibly with observers from other government departments and executive agencies), who will advise the Department of Health on which applications are most suited to receive funding. The Panel will be informed by the reviewers’ comments and any responses made to these comments by the researchers. However, it is ultimately the responsibility of the Panel to make any funding recommendations to the Department of Health.

**Selection criteria**

59. Criteria used by peer reviewers and members of the Commissioning Panel to assess applications for funding from the PRP include:

- **RELEVANCE** of the proposed research to the research specification
- **QUALITY** of the research design
- **QUALITY** of the work plan and proposed management arrangements
• **STRENGTH** of the research team
• **IMPACT** of the proposed work
• **VALUE** for money (justification of the proposed costs)
• **INVOLVEMENT** of patients and the public

**Timetable**

60. It is anticipated that commissioning of this research will occur to the following approximate timetable:

- Issue of invitation to tender: 28 May 2013
- Deadline for receipt of full applications: 23 July 2013
- Peer review to be completed: 12 August 2013
- Notification of outcome: November 2013
- Award of contract: December 2013 (subject to pre-contract negotiations)

61. In order to maximise the benefit from the findings, the research will need to commence as soon as possible following selection of the successful bid and placing of a contract. Capability to start promptly will be an advantage and should definitely be within 6 months of award of a contract.

**Contacts**

62. General enquiries regarding the application and commissioning process can be directed to the PRP CCF Help Desk by telephone at 0208 843 8027 or by email to prp@prp-ccf.org.uk
References and key documents


Department of Health (2012) *Final Stage Equality Analysis – proposals to introduce independent prescribing by podiatrists*,

http://www.npc.co.uk/improving_safety/improving_quality/resources/single_compet_framework.pdf


University of Southampton & Keele University, *Evaluation of nurse and pharmacist independent prescribing*,

Allied Health Professions Federation, *Outline Curricula Framework for Education Programmes to Prepare Physiotherapists and Podiatrists as Independent/Supplementary Prescribing and to Prepare Radiographers as Supplementary Prescribers*,


Publication pending

Health and Care Professions Council, *Standards for Prescribers*

Chartered Society of Physiotherapy, *Practice Guidance for Physiotherapist Supplementary and / or Independent Prescribers*

Society of Chiropodists and Podiatrists and Institute of Chiropodists and Podiatrists, *Good Practice for Prescribing and Medicines Management for Podiatrists*. 