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FOREWORD

This new course is available to third-year Medical, Veterinary and Natural Sciences (MVST) students as a ‘minor’ module. First launched in 2017, it has been updated and renamed this year. It offers students the opportunity to gain the knowledge, skills and practical experience to understand the importance and challenges of applied clinical research.

The module offers a platform for developing further expertise in academic medicine during clinical studies and beyond. Students will also have the opportunity to develop themes that they have begun to explore in this BBS module through Student Selected Components in Year 4 of the Cambridge clinical course.

About the Module

The module has two core components and one elective component.

Core Component 1: Lecture / Seminar Programme

Michaelmas Term

Weekly Lectures (1 hour):

Develop knowledge and understanding of applied clinical research. Topics are:

- The Nature/Importance of Applied Clinical Research
- Ethics and Research Governance and Patient Participation in Research
- Critical Appraisal 1
- Social Science Approaches
- Applied Health research Methods – a Map, Complex Interventions and an Introduction to the MRC Framework
- Experiments/Trials 1
- Observational Studies 1: Surveys and Mixed Methods
- Evidence Synthesis
- Experiments/Trials 2
- Observational Studies2: Case Control Studies and Cohort Studies
- Critical Appraisal 2

Weekly Group Seminars (2 hours)

Develop this new knowledge in the context of practical research issues and develop skills required for critical appraisal.

Both lectures and seminars will be delivered to the cohort of students as a single group at the School of Clinical Medicine on the Addenbrooke’s Site. Students will be guided to read relevant material and to self-direct their learning within this guidance framework.

Some course pre-reading for interested students will be provided.
Core Component 2: Current Research Issues and Methods: The Applied Component

Lent Term

Students will be attached to one of seven of the ten Primary Care Unit Research Groups. There will be an element of choice, depending upon different research groups’ capacity.

1. Applied Social Science Group
2. Behavioural Science Group
3. Behaviour and Health Research Group (not available)
4. Cancer Group
5. Cardiovascular Group
6. Clinical Nursing Research Group
7. Research Methods Hub (not available)
8. Palliative and End of Life Care Group
9. Prevention Group
10. Healthcare Improvement Studies (The Healthcare Improvement Studies (THIS) Institute) (not available)

The attachment is intended to deepen their study and critical appraisal of current research questions and methods in a specific field of applied clinical research; and view the application of methods in relevant studies, and the challenges and rewards of conducting research.

Elective Component: Dissertation

Students can undertake their Part 2 Dissertation in this module. Those who choose to do so will prepare a 6,000 word Research Protocol derived from this period of study.

All students (whether they elect to undertake their dissertation in this Module or not) will have the opportunity to return to their Research Group to continue their studies during Student Selected Components of their Clinical Course.

Find out more about research in the Primary Care Unit

Website:  http://www.phpc.cam.ac.uk/research/
YouTube:  https://www.youtube.com/channel/UCsTMogcSCwy5ITmF7xvPowq
Facebook: @pcucambridge
Twitter:  https://twitter.com/PCU_Cambridge

More information about the BBS options

About the course fair for second year MVST students
See more about the BBS courses and how they are organised here
1. INTRODUCTION

The aim of the module is to provide students with knowledge, skills and practical experience to understand the importance and challenges of applied clinical research and to offer a platform for developing further expertise in it during their clinical studies and beyond. Should they wish, students will be able further to develop their work in this module, through Student Selected Components in Year 4 of the Cambridge Clinical Course.

The module is delivered by researchers within the Primary Care Unit and draws on local strengths within that unit on working with large databases, Primary Care-based clinical trials and a range of other applied methods of quantitative and qualitative data collection and analysis. Throughout the course, students are able to draw on the research expertise within the Primary Care Unit and wider expertise in the University. A variety of teaching and learning methods are used, including lectures, group seminars, one to one/two supervisions and self-directed learning.

The course is open to applicants from both MVST and NST, although it is anticipated that it is likely to appeal more to the former. There are no essential or desirable pre-requisite courses that applicants should have studied previously in either Tripos. The maximum number of students per year is nine. The selection criteria (if required to be applied) can be found on the BBS Webpage:

https://www.biology.cam.ac.uk/undergrads/nst/bbs/Minors/129Selection

Students have the option to undertake an additional dissertation, supplementary to the course’s core material.

2. MODULE ORGANISATION

2.1 Module Organiser

Dr Juliet Usher-Smith, University Lecturer
The Primary Care Unit, Department of Public Health and Primary Care, Forvie Site, Robinson Way, CB2 0SR

2.2 Module Administrator

Mark Jenkins, GP Education Group Administrator
The Primary Care Unit, Department of Public Health and Primary Care, Forvie Site, Robinson Way, CB2 0SR

E: mj515@medschl.cam.ac.uk
T: 01223 (7) 62512

3. MODULE ENVIRONMENT

3.1 The Primary Care Unit (http://www.phpc.cam.ac.uk/pcu/)

Established in 1997 by the Foundation Professor of General Practice, Ann Louise Kinmonth, the Primary Care Unit (PCU) encompasses a number of multidisciplinary research groups and those responsible for undergraduate teaching in General Practice and Primary Care. The PCU forms part of the Department of Public Health and Primary Care (DPHPC).

The PCU has doubled in size in the last five years, with the appointment of five new professors and the acquisition of over £85m of research funds. We are one of the most productive Primary Care units in the UK, with a high volume of publications in peer reviewed scientific journals and a high level of impact on clinicians, NICE guidelines, central and local government health policies and the work of charities and NGOs plus a wide range of activities to inform the public and patients and carers.
The PCU has established itself as one of the UK’s strongest research groupings in behavioural science and Primary Care, and has built an international reputation for its work on the development and trial evaluation of theory-based preventive interventions, particularly in the areas of diabetes and cardiovascular disease.

The research strategy of the PCU is core to that of the overall DPHPC. We focus on understanding the determinants of behaviour, translating knowledge about risk factors and mechanisms into preventative and management strategies for chronic diseases, and testing these strategies in populations and settings representative of Primary Care. Particular areas of interest are risk communication, behaviour change, and randomised controlled trials of interventions in Primary Care settings. We work with other units and departments across the University of Cambridge that have complementary skills to our own, for example in conducting trials, measuring behaviour, statistics, development of innovative diagnostic tests and neuroscience. We also benefit from strategic partnerships nationally and internationally.

Our research has had a major impact on Primary Care practice and health policy. It has influenced national and international guidelines on atrial fibrillation, heart failure, hypertension, diabetes, and end of life care. It has informed government policy (e.g. on alcohol use) and underpinned the way in which quality of care in general practice is now measured. Examples of key studies include MoleMate, which was a randomised trial of different ways for Primary Care to diagnose melanoma, and ADDITION-Cambridge, which was the first randomised trial of screening for type 2 diabetes.

Research training is also core to our activities. We have trained, or are training, over 20 junior academic general practitioners through the NIHR Academic Clinical Fellowship (ACF) Scheme; notably they have published over 30 papers from their ACF research. There is also an integrated education programme for doctoral and pre-doctoral postgraduate students - over the last five years we have had 30 PhD students and we have developed a bespoke Masters in Primary Care Research which we now deliver alongside the existing Masters in Public Health and Epidemiology.

3.2 Department of Public Health and Primary Care (http://www.phpc.cam.ac.uk/)

The Department of Public Health and Primary Care (DPHPC) is one of Europe’s leading academic departments of population health sciences. It has been headed by Professor John Danesh since 2001 and comprises over 350 staff and graduate students. Groups in the Department are underpinned by major programme grants, such as those from the UK Medical Research Council (MRC), the Wellcome Trust, the British Heart Foundation (BHF), Cancer Research UK, the UK National Institute of Health Research, the European Union, the US National Institutes of Health, industrial partnerships, and several other sources.

The DPHPC takes great pride in its contributions to academic capacity in epidemiology, public health and Primary Care. It provides excellent training and educational programmes in biostatistics, epidemiology, public health, and Primary Care, at both undergraduate and graduate levels, including training of Academic Clinical Fellows. Presently, there are about 48 doctoral students and about 30 Masters’ students. Students in the DPHPC are typically supported by prestigious awards, such as studentships from the MRC, BHF, CRUK, Gates-Cambridge Trust, NIH-Cambridge Fellowships and GSK.

The DPHPC’s overall research objective is to generate scientific evidence that will inform the prevention of premature death and disability, the promotion of health, and provide evidence-based health policy. There is a particular focus on common chronic conditions such as common cancers, cardiovascular disease, neurodegenerative diseases, osteoporosis, and metabolic diseases.

Key strategies involve establishing large-scale population resources to enable investigation of the separate and combined influences of genetic and lifestyle factors in chronic diseases. The goal is to translate this evidence into the development and evaluation of preventative interventions.
4. MODULE OBJECTIVES

Following this module, all participating students will be able to demonstrate:

1. Knowledge and understanding of the applied clinical research context and the strengths, weaknesses and applicability of a range of research methods in key areas of the field

2. Ability to critically appraise a paper describing applied clinical research undertaken

3. Ability to critically discuss current issues, challenges and methods in a specific field of applied clinical research

Students undertaking their Part II dissertation in this module will, in addition, be able to demonstrate:

4. Ability to write a protocol for a research project, applying contemporary research methods to a clinically relevant area of investigation

5. MODULE OVERVIEW

The module will comprise two core components and one elective component:

5.1 Core Component 1: Lecture / Seminar Programme

During the Michaelmas term, students will attend weekly lectures and group supervisions. Lectures will offer a basis of knowledge and context. Group supervisions will develop this knowledge in the context of practical research issues and teach skills required for critical appraisal. Both lectures and seminars will be delivered either in the Primary Care Unit or School of Clinical Medicine to the cohort of students as a single group. Students will be guided to read relevant material and to self-direct their learning within this guidance framework.

5.2 Core Component 2: Study of current research issues, challenges and methods in a selected field: the applied component

During the Lent term students will work with one allocated PCU research group, in whose field they will deepen their study and critical appraisal of current research questions and methods, view the application of methods in relevant studies, and the challenges and rewards of conducting applied clinical research. Students will discuss their preferences with the course organiser and be allocated to a research group by 25/10/20.

Students will attend weekly one to one or small group supervisions with a supervising member of the research group. Students may also have the opportunity to attend project team meetings and to observe data collection and analysis. There will be no requirement for new ethical or research governance approval for students to undertake this work.

Students will be guided to read relevant material and self-direct their learning within this guidance framework. There will be no requirement for additional supervisions in addition to those delivered by the PCU.

5.3 Elective Component: Dissertation

Students wishing to undertake their Part 2 Dissertation in this module will be able to do so by preparing and submitting a 6,000 word Research Protocol derived from this period of study. A dissertation will normally be undertaken and supervised within the research group to which a student is allocated for the
core component of the course. Students considering this option should start to plan as soon as possible once the module begins. Students will have the opportunity to discuss their research group and dissertation options with the Module Organiser before the deadline for confirmation.

Students should specify their intention, and where taking this option, identify an initial dissertation title by Thursday 5th November 2020, to allow them to inform the Faculty of Biology of their choice by the specified deadline of Friday 6th November 2020.

The deadline for modifications to the dissertation title is Friday 19th March 2021. The deadline for submission of the dissertation is Friday 30th April 2021.

All students (whether they elect to undertake their dissertation in this module or not) will have the opportunity, should they wish, to return to their Research Group to continue their studies during Student Selected Components of their Clinical Course.

6. MODULE ASSESSMENT

Module assessment will be set and marked by a University Internal Senior Examiner. Marking will be supported by a University Second Examiner. The assessment process will be reviewed by a University External Examiner. Examiners will follow the Faculty of Biology Examiner Code of Conduct, available at: https://www.biology.cam.ac.uk/undergrads/exams/exam-conduct.

6.1 Core Assessment: All Students

Core modules will be assessed by one written paper of three hours duration, with three sections. Each section will carry equal marks.

**Question 1 (1 Hour):**
- **Question area:** Research methods, their strengths, weaknesses and applicability.
- **Question format:** 3 short answer questions, from a choice of 5. 10 marks for each question, total 30 marks
- **Mark Scheme:** Agreed by examiner team, questions double marked, final mark agreed between examiners.

**Question 2 (1 hour):**
- **Question area:** Critical appraisal of an applied clinical research paper.
- **Question format:** Several compulsory questions relating to a single research paper. Total 30 marks.
- **Mark Scheme:** Agreed by examiner team, questions double marked, final mark agreed between examiners.

**Question 3 (1 Hour):**
- **Question area:** Current issues, challenges and methods in a specific field of applied clinical research.
- **Question format:** 1 essay question, from a choice of 2. Total 30 marks
- **Mark Scheme:** Agreed by examiner team, question double marked, final mark agreed between examiners.

Final stratification of overall results will be based upon the Faculty of Biology guidance for marking Tripos essays, available at: https://www.biology.cam.ac.uk/undergrads/exams/marking-tripos-essays/marking-tripos-page

One formative practice question paper, marked and returned to students with feedback, will be set at the beginning of the Lent Term. General advice for students about how to approach examinations is available at: https://www.biology.cam.ac.uk/undergrads/exams/skills.
6.2 Elective Dissertation Assessment

Students who elect to take their Part II Dissertation in this module will be required to write a 6,000 word written Project Protocol addressing an applied clinical research question.

Guidance for dissertation supervisors is available at: https://www.biology.cam.ac.uk/colleges/supervisors/supervising-dissertations

Students will be expected to follow the Faculty of Biology dissertation guidelines, available at: https://www.biology.cam.ac.uk/undergrads/nst/bbs/dissertations.

Specifically, according to these guidelines, students should receive a maximum of four supervisions with their dissertation supervisor. Students are expected to meet with their supervisor a minimum of two times during the preparation of their dissertation. Supervisors are only permitted to view a single draft of a dissertation prior to submission.

Dissertations will be double marked. Final stratification of overall results will be agreed between Examiners and based upon the Faculty of Biology guidance for marking Tripos essays, available at: https://www.biology.cam.ac.uk/undergrads/exams/markings-part-ii-dissertations/markings-diss

It is anticipated that the structure of a research protocol will include the following sections: Summary (300 words maximum), Background, Aims, Methods, Timeline, and References. Students are not obliged to use these actual headings and may choose to further divide some of these components into contributory sections. Students may find it helpful to use or adapt templates for research protocols in different research areas, available at: http://www.equator-network.org/.

Advice on preparing the dissertation is available at: https://www.biology.cam.ac.uk/undergrads/nst/bbs/dissertations#section-9

Further advice, specific to this module is as follows:

1. Be sure to take special care in setting out tables and figures. Be certain to run text through a spell checker. Back work up.

2. The ‘summary’ (300 words maximum) should crisply encapsulate the entire research protocol for a reader who is intelligent, but unfamiliar with the field.

3. The ‘background’ section should establish the starting point for the enquiry by summarising the current state of knowledge relevant to the specific question, (which will be stated in the subsequent ‘Aims’ section).

4. The ‘background’ section should follow the Faculty of Biology style guide and will include a review of the existing literature. This should clearly demonstrate an ability to find the relevant literature and to critically appraise its content. However, the background section should not be expanded uncritically. Keep it in balance with the other sections.

5. The ‘background’ section should conclude with a summary that bridges to the work that is to follow. with clear statements of the aim and, if appropriate, the hypothesis to be tested e.g. “Because of the uncertainty about the role of X in condition Y, we set out to see whether levels of X were associated with risk of Y in our study population Z.

6. The ‘aims’ section should state the central question(s) clearly at the beginning and serve as the basis on which to plan the methods and timeline. If the research question involves a hypothesis, it should be stated clearly here.
7. The ‘methods’ section should describe the research plans in sufficient detail for a reader to replicate them. Explicitly consider ethical issues and ways of addressing them.

8. Clearly describe the analytic strategy. It is important that the statistical or qualitative methods used to analyse data should be described clearly, with references when appropriate.

9. The timeline should be realistic in relation to the work proposed

Students should specify their intention, and where taking this option, identify an initial dissertation title by Thursday 5th November 2020, to allow them to inform the Faculty of Biology of their choice by the specified deadline of Monday 9th November 2020.

The deadline for modifications to the dissertation title is Friday 19th March 2021. The deadline for submission of the dissertation is Friday 30th April 2021.
7. MODULE SCHEDULE

7.1 Core Component 1 – Lecture/Seminar Programme: Research Context, Methods and Critical Appraisal

Michaelmas Term runs from Tuesday 6th October to Friday 4th December 2020

From Statutes and Ordinances of the University of Cambridge

All lectures and seminars will be held at the Clinical School unless otherwise stated

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Timing</th>
<th>Topic</th>
<th>Developed and delivered by</th>
<th>Teaching</th>
<th>Reading</th>
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<tr>
<td>Mon 05/10/20</td>
<td>Mic'mas Wk 1a</td>
<td>The Nature/Importance of applied clinical research</td>
<td>Dr Juliet Usher-Smith</td>
<td>1hr Lecture</td>
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<td>Tues 06/10/20</td>
<td>Mic'mas Wk 1c</td>
<td>Ethics, Research Governance and Patient Participation in research</td>
<td>Dr Stephen Barclay</td>
<td>2hr Lecture</td>
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<td>Thurs 08/10/20</td>
<td>Mic'mas Wk 1d</td>
<td>Critical Appraisal 1</td>
<td>Prof Martin Roland</td>
<td>1 hr Lecture</td>
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<td>Mon 12/10/20</td>
<td>Mic'mas Wk 2</td>
<td>Social Science Approaches</td>
<td>Dr Robbie Duschinsky</td>
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<td>Thurs 15/10/20</td>
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<td>Applied health research Methods – a Map, Complex Interventions and an Introduction to the MRC Framework</td>
<td>Prof Christi Deaton</td>
<td>1hr Lecture</td>
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<td>Mon 19/10/20</td>
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<td>Experiments/Trials 1</td>
<td>Prof Simon Griffin</td>
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<td>Thurs 22/10/20</td>
<td>Mic'mas Wk 5</td>
<td>Observational Studies 1: Surveys and Mixed Methods</td>
<td>Dr Anna Spathis</td>
<td>1hr Lecture</td>
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<td>Mon 26/10/20</td>
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<td>Dr Fiona Walter</td>
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<td>Prof Stephen Sutton</td>
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<td>Evidence synthesis</td>
<td>Dr Fiona Walter</td>
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<td>Experiments/Trials 2</td>
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**7.2 Core Component 2: Study of current issues, challenges and methods in a specific field of GP and Primary Care Research**

Michaelmas Term runs from Tuesday 6th October to Friday 4th December 2020
*From Statutes and Ordinances of the University of Cambridge*

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<th>Topic</th>
<th>Developed &amp; delivered by</th>
<th>Teaching</th>
<th>Reading</th>
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<td>Mic’mas Wks 1-7</td>
<td>Choosing and organising attachment to a research group</td>
<td>Self-directed activity</td>
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<tr>
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<td>Mic’mas Wk 1</td>
<td>Research group and dissertation choice discussion</td>
<td>Module Organiser</td>
<td>1hr meeting</td>
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<td>15.00-16.00</td>
<td>Mon 19/10/20</td>
<td>Research group and dissertation choice catch-up discussion</td>
<td>Module Organiser</td>
<td>1hr meeting</td>
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<tr>
<td>15.00-16.00</td>
<td>Tues or Thurs PM</td>
<td>Total time</td>
<td>2hrs meeting</td>
<td></td>
</tr>
</tbody>
</table>

Lent Terms runs from Tuesday 19th January to Friday 19th March 2021
*From Statutes and Ordinances of the University of Cambridge*

<table>
<thead>
<tr>
<th>Timing</th>
<th>Topic</th>
<th>Developed &amp; delivered by</th>
<th>Teaching</th>
<th>Reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tues or Thurs PM, negotiated with host research team</td>
<td>Lent Wks 1-8</td>
<td>Study of current issues, challenges and methods in a specific field</td>
<td>Experienced post-docs with UTO oversight</td>
<td>1hr / week supervision</td>
</tr>
<tr>
<td>Tues PM Date/time to be confirmed</td>
<td>Lent Wks 1-8</td>
<td>Meeting on practice exam paper and prep for exam</td>
<td>Module Organiser</td>
<td>1hr meeting</td>
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<tr>
<td>Total time</td>
<td></td>
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<td>9hrs Supervision/Meeting</td>
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<td></td>
<td></td>
<td></td>
<td>80hr Reading</td>
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</tbody>
</table>
7.3 Elective Component: Dissertation

| Lent Weeks 1-8 | Development of a Research Protocol  
| NB: Friday 19th March is the deadline for modifications to the dissertation title  
| Friday 30th April is the deadline for submission of the dissertation | Experienced post-docs with UTO oversight | Min 2 to max 4 supervisions in total |

7.4 Optional reading on Statistics

Following student feedback on cohort 1 some optional statistical reading is available for students to access during the summer holidays. These are:

Kirkwood, B and Sterne, J *Essentials of Medical Statistics* (2nd Edition), Blackwell Publishing


ISBN: 1 85996 219 x (Print Edition)


BMJ Statistics Notes: [http://www.bmj.com/specialties/statistics-notes](http://www.bmj.com/specialties/statistics-notes)

University of Cambridge Training Courses:

[https://training.cam.ac.uk/search?query=Statistics](https://training.cam.ac.uk/search?query=Statistics) includes *Statistics for the Terrified*
8. LECTURE/SEMINAR PROGRAMME CONTENT

8.1 The Nature/Importance of Applied Clinical Research
Dr Juliet Usher-Smith, University Lecturer, The Primary Care Unit, Department of Public Health and Primary Care

Lecture (1 Hr)

This lecture will provide an introduction to the course and the nature and importance of applied clinical research. This will include discussion of what is meant by applied clinical research, the role of applied clinical research, and the relationship between research, clinical practice and service evaluation.

Reading (2 Hr)

8.2 Ethics, Research Governance and Patient Participation in Research
Dr Stephen Barclay, University Senior Lecturer in General Practice and Palliative Care, Primary Care Unit, Department of Public Health and Primary Care

Lecture (1 Hr)

This lecture will be interactive, with contributions from Dr Barclay, a current member of the Palliative Care Research Group’s PPI (Patient and Public Involvement) Group and students. It will provide an introduction to the ethical concepts, legislative requirements and practical considerations when carrying out applied clinical research and the principles of PPI. After an introduction to the principles of ethics, research governance and PPI, students will consider:

- the ways in which PPI members can contribute to all the stages of the research process, including the process to gain relevant study approvals
- the benefits of PPI involvement
- the potential pitfalls of PPI involvement
- the key factors that lead to successful PPI involvement

Reading (4 Hr)

Ethics in Medical Research: http://www.sciencedirect.com/science/article/pii/S2213879X14000224

Browse this website: Health Research Authority http://www.hra.nhs.uk

The patient voice in research: evolution of a role
Johnson et al. Research Involvement and Engagement (2016) 2:6

Practical considerations in improving research through public involvement
Jenner et al. Research Involvement and Engagement (2015) 1:3
DOI 10.1186/s40900-015-0002-y

More than just ticking a box…how patient and public involvement improved the research design and funding application for a project to evaluate a cycling intervention for hip osteoarthritis
DOI 10.1186/s40900-015-0013-8
8.3 Critical Appraisal
Prof Martin Roland CBE, Emeritus Professor of Health Services Research, Primary Care Unit, Department of Public Health and Primary Care

Lecture (1 Hr)
Throughout your lives, you will read many scientific papers in medical journals. These will form the foundation of much of what you learn in medical school and continue to learn throughout your professional career. Some of these will come from journals that you take personally, e.g. the BMJ or the journal of your own specialist society. Others will come to your attention through third parties, e.g. the press, blogs, podcasts, social media etc.

How do you decide which of these papers are relevant to your own practice? Are the findings reliable? How well founded are the authors’ conclusions? Are they relevant to you? Do the headline summaries in the press represent correct conclusions when applied to the patients you see day to day?

Underpinning your answers to these questions lies the basic skill of being able critically to read a paper and the ability to decide how and whether a paper should influence what you believe, understand and carry into clinical practice. This introductory lecture, the accompanying lecture notes and the two hour practical session that comes later in the term aim to give you these skills – ones which you will use throughout your student and later professional life.

Reading
Greenhalgh T. How to Read a Paper: The Basics of Evidence-Based Medicine. 6th edition (although earlier editions are very similar). Chapter 1: Why read papers at all? and Chapter 3: Getting your bearings – what is this paper about? Wiley Blackwell. 2019. Students may also find other Chapters in this book useful throughout the course.

Seminar (2Hr)
In advance of the seminar you will be given three papers to read. Accompanying the papers will be a series of questions (e.g. ‘Do you think the conclusions drawn by the authors are justified?’ ‘What other methods could have been used to answer this research question?’ ‘Do you think the findings of the paper could be extrapolated to other patient groups?’). In this way, the seminar will give you practice at critical reading skills as well as drawing together what you’ve learned about research methods covered in other lectures and seminars.
8.4 Social Science Approaches
Dr Robbie Duschinsky, University Senior Lecturer, Head of the Applied Social Science Group, Primary Care Unit, Department of Public Health and Primary Care

Lecture (1 Hr)
The lecture will provide an introduction to the use of social science methods and theories within applied clinical research. The lecture will begin by considering different kinds of knowledge, and their role within research. The advantages of social science approaches will be highlighted for studying patient perspectives, and for exploratory research addressing processes and practices. Qualitative and quantitative social science methodologies discussed will include interviews, observational measures and longitudinal study. The lecture will also consider reasons why it is important to think about clinical practice within the context of wider social forces and social values, and how social theory can help with this. The final part of the lecture will present a selection of exemplar social science studies, demonstrating the diversity and value of what can be achieved through such approaches, whether on their own or within a wider research programme.

Reading (4 Hr)

Plus one of the papers listed below.

Seminar (2 Hr)
Students are asked to select one from among of the varied group of papers below. In the seminar, each student will present briefly on: a) how the methodology facilitates the contribution or value of the paper; b) the kind of knowledge the paper offers; c) the paper’s implications. Group discussion will explore the advantages and limitations of particular approaches within the social science toolkit for research on challenges within clinical practice.

4) Dumit, J. (2006) Illnesses you have to fight to get: facts as forces in uncertain, emergent illnesses. Social Science & Medicine, 62(3): 577-90

In addition to the reading list provided by Robbie Duschinsky, students are given five papers on qualitative research. These are essential reading and you are encouraged to be familiar with them in preparation for the exam. These are:

1 Barbour, R, Checklists for improving rigour in qualitative research: a case of the tail wagging the dog BMJ 2001; 322: 1115-7

3 Pope, C, Ziebland, S and Mays, N, *Qualitative research in health care – Analysing qualitative data* BMJ 2000; 320: 114-6

4 Meyer, J, *Qualitative research in health care – Using qualitative methods in health related action research* BMJ 200; 320: 178-81

5 Varpio et al, *Shredding the cobra effect: problematizing thematic emergence, triangulation, saturation and member checking*, Medical Education 2017: 51: p40-50
8.5 Applied Health Research Methods – a Map, Complex Interventions and an Introduction to the MRC Framework

Prof Christi Deaton, Florence Nightingale Foundation Chair of Clinical Nursing Research, Primary Care Unit, Department of Public Health and Primary Care

**Lecture (1 Hr)**

The lecture will provide students with an introduction to methods used in applied clinical research and complex interventions. Students will gain an appreciation of the value of theory and multiple methods in developing, testing, implementing and evaluating interventions. Content will provide context and a basic understanding on which to build in subsequent methodological lectures in the term. The Medical Research Council (MRC) Framework for Complex Interventions, and process evaluation of complex interventions will be discussed. Students will consider the reasons why interventions and service improvements fail, or cannot be replicated or scaled.

**Reading (4 Hr)**


**Seminar (2 Hr)**

The seminar will reinforce the key messages of the lecture through critical appraisal of development and testing of a complex intervention. Students will read two papers on the same complex intervention, and discuss the development, theoretical frameworks, and methods used to evaluate the intervention. Group discussion will guide the students in critical appraisal of the intervention, study methods and results.

**Readings:**

Duane S, Callan A, Galvin S, Murphy AW, Domegan C, O'Shea E, Cormican M, Bennett K, O'Donnell M, Vellinga A. Supporting the improvement and management of prescribing for urinary tract infections (SIMPle): protocol for a cluster randomized trial. Trials. 2013; 14: 441. [http://www.trialsjournal.com/content/14/1/441](http://www.trialsjournal.com/content/14/1/441)

8.6 Experiments/Trials 1
Prof Simon Griffin, Professor of General Practice, Primary Care Unit, Department of Public Health and Primary Care

Lecture (1 Hr)

The lecture will provide a basic understanding of the commonly used designs of randomised controlled trials as well as the organisation, conduct, monitoring, analysis and reporting of a randomised clinical trial in Primary Care. It will focus on why clinical trials are performed, discover their advantages and disadvantages and the safeguards that are employed to ensure that participants are not exposed to unnecessary risk. It will offer insights into how qualitative work can contribute to clinical trials. It will also cover the need for evaluation of costs of treatment, some of the difficulties associated with this, and how data on effectiveness and costs are combined to determine cost-effectiveness. Examples will range from trials of medication used in General Practice through to behavioural and policy interventions.

Reading (4 Hr)


Seminar (2 Hr)

The seminar will focus on the critical appraisal of a clinical trial relevant to applied clinical research. Students will be provided with a short paper in advance and expected to read around topic areas. Group discussion will focus on the methodological quality of the trial and the clinical relevance of the results.

Reading:

8.7 Observational Studies 1: Surveys and Mixed Methods
Prof Mary Dixon-Woods, Director and Dr Jenni Burt, Senior Social Scientist, THIS Institute

**Lecture (1 Hr)**

This lecture will identify the value of mixed-method approaches for addressing many research questions in applied clinical research, including those that involve evaluation of complex interventions. It will explain the principles underlying programme evaluation, including how use of a theory-oriented approach supports clearer specification of interventions, mechanisms and outcomes as well as integration of multiple forms of evidence.

**Reading (4 Hr)**


O’Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. *Bmj*. 2010 Sep 17;341:c4587


**Seminar (2 Hr)**

The seminar will explore how to develop and specify a programme theory for the intervention and a plan for study in primary care. The study will use mixed methods and will include a questionnaire. Students will appraise commonly-used techniques for item generation, sampling, and statistical analysis of questionnaire data. Students will consider and define their target population, mode of administration, approach to recruitment, chosen risk prediction tool, questionnaire items, and analysis plan. They will consider how to integrate the questionnaire data with other forms of data.
8.8 Evidence Synthesis
Dr Fiona Walter, Principal Researcher in Primary Care Cancer Research, The Primary Care Unit, Department of Public Health and Primary Care

**Lecture (1 Hr)**

The basic concepts of systematic reviews and evidence synthesis for applied health care will be described, including different types of research methods. The strengths and weaknesses of different study designs will be considered, as well as how to critically appraise evidence for sources of bias, and applying evidence to applied health care settings. Examples will range from quantitative systematic reviews to data synthesis (meta-analysis and qualitative), and realist reviews.

**Reading (4 Hr)**


**Seminar (2 Hr)**

The seminar will further explore the issues raised in the lecture through critical appraisal of a systematic review. Students will be provided with a short paper to be read in advance of the seminar, and expected to read around the topic area. Group discussion will focus on the methodological quality of the systematic review and the clinical relevance of the findings.

**Reading:**

Greenhalgh T. Papers that summarise other papers (systematic reviews and meta-analyses). BMJ : British Medical Journal. 1997; 315(7109):672-675

8.9 Experiments/Trials 2
Prof Stephen Sutton, Professor of Behavioural Science, Primary Care Unit, Department of Public Health and Primary Care

Lecture (1 Hr)

This lecture will discuss randomised controlled trials of behavioural interventions and some of the special considerations that arise in this context. Frameworks for developing behaviour change interventions, including the role of theory, will be described. Risk of bias in behavioural intervention trials will be covered. The problems of measuring behavioural outcomes will be discussed, including measurement reactivity. The wider issue of trial participation effects will also be considered. Examples will include trials of interventions to increase physical activity.

Reading (4 Hr)


Seminar (2 Hr)

The seminar will focus on ‘digital’ interventions for behaviour change e.g. text messaging interventions, electronic monitoring and feedback, smartphone apps. Such interventions may require different methods of development and evaluation. For example, it has been suggested that the traditional randomised controlled trial may not be an appropriate method for evaluating the effectiveness of digital interventions. Students will be provided with a short paper in advance and expected to read around the topic.

Reading:

**8.10 Observational Studies 2: CPRD, Case Control Studies and Cohort Studies**  
Prof Jonathan Mant, Head of the Primary Care Unit, Department of Public Health and Primary Care

**Lecture (1 Hr)**

The purpose, design, analysis and limitations of case control and cohort studies will be described. The advantages and disadvantages of using these designs to explore effectiveness in the context of applied clinical research will be considered. Examples will include studies using the Clinical Practice Research Datalink (CPRD), a large data-set derived from routine general practice data.

**Reading (4 Hr)**

Dawes M et al, Evidence based practice: a primer for health care professionals. 2nd edition, Chapter 8: Case control and cohort studies. Elsevier Ltd 2005

**Seminar (2 Hr)**

The seminar will further explore the issues raised in the lecture through appraisal of two papers, to be read in advance of the seminar.


9. Student Selected Component (SSC) Descriptions for Core Component 2

Research Group 1: Applied Social Science Group

Research Head: Dr Robbie Duschinsky

Supervisor: Lianne Bakkum

Summary:

There are many antecedents/risk factors for depression among children and young people. Some of these are individual-level factors such as age, gender, and physical illness. However, especially for young people, family-level factors can be important for predicting the onset and duration of depressive symptoms. This SSC project will be to contribute to a review of evidence relating to familial risk factors for adolescent depression with a focus on the following variables: parental or sibling mental illnesses, parental or sibling long-term physical illnesses or disabilities, and change in family structure due to bereavement or end of parental cohabitation. The overall project, of which this review is a component, is a collaboration with colleagues at UCL and Bristol Universities in work to construct a risk prediction tool for adolescent depression adapted for use in primary care settings.

Reading List:


Research Group 2: Behavioural Science Group

Research Head: Prof Stephen Sutton

Supervisor: Prof Stephen Sutton or Dr Katerina Kassavou

Summary:

In the Behavioural Science Group, we develop and evaluate interventions to change behaviours such as smoking, physical activity and medication adherence. The interventions include very brief face-to-face interventions delivered by healthcare practitioners and 'digital interventions' using text messaging, automated telephone interventions or smartphone apps. Student projects are likely to involve conducting a relevant systematic review (e.g. a review of studies of the effectiveness of digital interventions for medication adherence) or analysing existing qualitative or quantitative data (e.g. on patients' or practitioners' views on using digital technologies for behaviour change).

Reading List:


Holender A, Sutton S, De Simoni A. Opinions on the use of technology to improve tablet taking in people on cardiovascular medications: insights from people over 65 attending two London community centres. *Journal of International Medical Research* Published online 6 May 2018
Research Group 3: Cancer Group

Research Head: Dr Fiona Walter

Supervisor: Dr Fiona Walter and a team member

Summary:

In the Cancer Group, we develop and evaluate interventions to improve diagnostic strategies for cancer, patient experiences of cancer diagnostic pathways, and their clinical outcomes.

The interventions are all for the primary care population, and include: existing tests which have not yet been shown to be accurate or effective such as Ca125 for women with possible symptoms of ovarian cancer; new tests such as Faecal Immunochemical Tests (FITs) for patients with possible symptoms of colorectal cancer, and the Cytosponge for people with symptoms of Barrett’s Oesophagus, a precursor of oesophageal cancer; technological or digital interventions such as smartphone apps and dermoscopy for patients with possible symptoms of skin cancer; and inequalities in the diagnostic pathway such as for women with later renal and bladder cancer diagnoses than men.

Student projects are likely to involve conducting a relevant systematic review, or analysing existing qualitative or quantitative data (e.g. on practitioners’ views on using digital technologies for monitoring skin symptoms).

Reading List:


Research Group 4: Cardiovascular Group

Research Head: Prof Jonathan Mant

Supervisor: 1) Dr Jenny Lund 2) Ryc Aquino

Summary:

OPTION 1:

The attachment would offer the student the opportunity to experience a major national trial investigating the potential of screening for atrial fibrillation as a method for stroke prevention. Further details of the trial can be found here: http://www.phpc.cam.ac.uk/pcu/research/research-projects-list/other-projects/safer/

The student would particularly be attached to the pilot study investigating the frequency of ECG recording with the trial device and how this affects the yield of AF detected. There would be the opportunity to experience quantitative work on the yield of AF detected and qualitative work through the focus groups and questionnaires planned to investigate the psychological impact of screening on trial participants. There is also the potential to experience the use of general practice 'big data' via research questions involving CPRD. Within the project the student will gain skills in using STATA statistical package. The specific research question the student will be working on can be adapted to their particular interest.

OPTION 2:

The proposed attachment will offer a student to be involved in an aspect of a randomised controlled trial assessing the effectiveness of a novel model of primary care for stroke survivors (http://www.phpc.cam.ac.uk/pcu/research/research-projects-list/other-projects/ipcas/)

In particular, the student would be involved in activities relating to the assessment of intervention fidelity defined as the extent to which the intervention is delivered as planned. This work is especially important in General Practice and Primary Care Research where practices might uniquely adapt the intervention being tested to their current context. There will be an opportunity to be involved in quantitative and qualitative work, to explore how the new model of care is implemented in practice. The participating student may gain skills in interviewing and data analysis. There is the potential for the student to develop their own research question concerning intervention fidelity methods.
Research Group 5: Clinical Nursing Research Group (CNRG)

Research Head: Prof Christi Deaton

Supervisor: Prof Christi Deaton or a delegated member of the current team

Summary:

Objective: Ability to critically discuss current issues, challenges and methods in a specific field of General Practice and Primary Care Research

The CNRG is currently conducting the Optimising Management of Patients with Heart Failure with Preserved Ejection Fraction (Optimise HFpEF) study, and the RESTORE study focusing on increasing referral and uptake of patients with COPD to pulmonary rehabilitation. A student would have the opportunity (if necessary approvals in place) to observe the assessment of patients with HFpEF enrolled in the cohort study and/or interviews with patients who have been hospitalised and carers of patients with HFpEF. They would be able to read anonymised transcripts of interviews and participate in data analysis. In the spring of 2019 we will be conducting some consensus work through nominal groups with clinicians and patients/carers so they would have the opportunity to observe this process.

A student would be able to attend team meetings, and potentially contribute to literature reviews or other papers and reports that are being written at that time. Synthesising and disseminating the information produced by Optimise HFpEF to those participating in the consensus work will be a major challenge during 2019, and students may have the opportunity to be involved.
Research Group 6: Palliative Care and End of Life Group

Research Head: Dr Stephen Barclay
Supervisor: Dr Stephen Barclay

Summary:

43% of all deaths in England and Wales occur in care homes or people’s own homes, under the care of their GP and Primary Health Care Team. In addition, most of the last year of life is spent at home under GP care. So Primary Care has a central place in the care of people approaching and at the end of their lives. The Palliative and End of Life Care group has a number of research studies underway that students might be able to join in during the Lent Term: see the group’s website for further information. Feel free to contact Dr Barclay to discuss the possibilities that will be available.

Reading List:


**Research Group 7: Prevention Group**

Research Head: Prof Simon Griffin

Supervisor: Prof Simon Griffin or a delegated member of the current team

Summary:

Research interests and projects of the Prevention Group

The overall aims of the group are to:

1. Quantify the impact of health behaviours on outcomes, and identify determinants of health behaviours
2. Develop practical strategies to identify individuals or groups at increased risk of chronic disease and likely to benefit from interventions
3. Develop and evaluate ways to communicate information about health behaviours, risk factors and disease risk
4. Develop and evaluate interventions to reduce disease risk

Current projects include:

- Systematic reviews and external validation of existing risk prediction models for prostate cancer and colorectal cancer to inform the development of risk stratified screening programmes
- Developing personalised cancer risk information to promote behaviour change and the I-CaPP programme - developing very brief interventions for prevention of cancer in primary care
- A longitudinal qualitative study over ten years to explore patient views on patient-practitioner interactions in type 2 diabetes
- Multiple cohort analysis nested within the ADDITION-Cambridge trial to examine the impact of patient-centred care on CVD risk factor levels, incidence of CVD events and mortality, and health care costs in type 2 diabetes
- A qualitative interview study with practitioners and patients to investigate how and why consultations might influence health behaviours and outcomes in type 2 diabetes
- A review on screening for malnutrition among older people in the community
- 5- and 10- year follow-up of the ADDITION-Cambridge and ADDITION Plus studies to examine the impact of intensive treatment in individuals with screen detected diabetes
- Establishing the diagnostic validity of cardiovascular disease in primary, secondary and tertiary care and disease registry records using the ADDITION-Cambridge data
- A rapid evidence synthesis of the NHS Health Check programme

We also collaborate closely with colleagues within other groups in the Primary Care Unit and both nationally and internationally.

Student projects are likely to involve conducting a relevant systematic review, or analysing existing qualitative or quantitative data

Reading List: To be confirmed
10 GENERAL MATTERS

10.1 Attendance
All teaching will take place at the School of Clinical Medicine on Addenbrooke’s Hospital campus.

http://www.phpc.cam.ac.uk/pcu/files/2013/11/CBC-General_Sitemap_October-2016-LL.pdf

All students are expected to attend all lectures and related teaching sessions on time and may only be absent for unavoidable and valid reasons. Students are also expected to have undertaken background reading and other relevant work as preparation for each teaching session. It is the student’s responsibility to inform the Module Administrator (details below) and relevant Supervisors of an unavoidable absence and to complete all work missed due to absence. To monitor attendance and for the purposes of course evaluation, a record of attendance will be maintained for all teaching sessions.

10.2 Module Administrator
Mark Jenkins, GP Education Group Administrator
The Primary Care Unit, Department of Public Health and Primary Care, Forvie Site, Robinson Way, CB2 0SR
E: mj515@medschl.cam.ac.uk
T: 01223 (7) 62512

10.3 Recommended Reading
So far as possible the Module Administrator will make available the recommended reading either by email or online via the designated Moodle pages: https://www.vle.cam.ac.uk/course/view.php?id=149101

10.4 Stationary and Calculators
Students are expected to provide their own stationery.

It is not envisaged that students will need a calculator for the exam, but should they want to have one, they will need to get the correct calculator approved (with a yellow sticker) by their College Director of Studies as soon as possible, if they haven’t had it approved already. The University’s guidance in The Reporter is here.

10.5 Feedback and Evaluation
Student feedback is essential for continued development and evaluation of the module. Students will be asked to provide Google Form feedback on each lecture/seminar including rating of the sessions.

10.6 Travel Information
There is a bus service (Route U) that is subsided by the University for University cardholders that runs during the working day between Eddington and the University West Cambridge Site and the Addenbrooke’s Hospital. Website: https://www.cuh.nhs.uk/finding-us

There is no car parking facility for students at the Primary Care Unit.

10.7 Toilet Facilities/Lifts and Refreshments
Clearly signed accessible toilet facilities/lifts are available at the School of Clinical Medicine.
There is a café on the ground-floor of the School of Clinical Medicine, and there is a wide variety of shops/cafes in the main Addenbrooke’s Concourse.

10.8 First Aid
First Aiders are available by contacting the main reception at the School of Clinical Medicine.

10.9 Libraries
The Medical Library in the School of Clinical Medicine affords a wide spectrum of books and journals. WIFI is available in the School of Clinical Medicine – see Library Staff for details.

Students may also wish to use the main University Library on West Road, particularly in the area of government documents and more specialist material.

There are several other libraries within Cambridge University, e.g. the Scientific Periodical Library. Information on these is available on the University website http://www.cam.ac.uk/.

10.10 Useful Websites
The Primary Care Unit: http://www.phpc.cam.ac.uk/pcu/

General Practice Education Group:
http://www.phpc.cam.ac.uk/pcu/education-and-training-overview/gpeg-gp-teaching-for-medical-students/

School of Clinical Medicine: http://medschl.cam.ac.uk

Medical Library: http://library.medschl.cam.ac.uk/