

<b>Institution: Keele University</b>
<b>Unit of Assessment: UoA3</b>
<b>Title of case study: Medicines Management</b>
<p><b>1. Summary of the impact</b></p> <p>Research undertaken on prescribing strategy by the Centre for Medicines Optimisation (School of Pharmacy) is embedded in NHS policy for medicines management. Keele's bespoke reports for the West Midlands Region provided the template for national performance management of primary care prescribing. Linked educational outreach studies established the use of community pharmacists as change agents. Both of these approaches are referenced in separate National Audit Office reports. In addition, Keele piloted risk sharing between pharmaceutical companies and the NHS, now adapted in DH Joint Working Guidelines and NICE policy. Their work on effective shared care is referenced in the 2013 GMC guidance on good practice in prescribing. These principles have been adapted for their WHO government level reports.</p>
<p><b>2. Underpinning research</b></p> <p><u>Getting more from PACT (Prescribing Analysis and Cost) Data: Benchmarking, informing cost-effectiveness and linking prescribing to outcomes.</u></p> <p>The utility of PACT data to provide benchmarking of GP prescribing in a way that also informs pharmaco-economic modelling was established by Prof Chapman [1]. This paper describes how by analysing GP prescribing data and using basic denominators, prescribing patterns between health authorities can be compared. This was followed by a <i>BMJ</i> publication in 1996 showing how combining PACT data with observational data can provide estimates of potential public health effects – in this case potential adverse events associated with the use of minocycline [2]. This analysis also informed the cost/benefit discussion on the use of minocycline versus tetracycline as a systemic antibiotic treatment for acne. The value of linking prescribing information with patient outcome data for basic pharmaco-epidemiology work was further demonstrated by Shelley's work on inhaled corticosteroids for asthma, establishing the value of combining prescribing and outcomes data to develop useful 'prescribing benchmark indicators' [3]. The link with hospital admissions as proxy outcomes is an early example of the shift from medicines management (basic cost minimisation) to medicines optimisation. Further research using the General Practice Research Database (GPRD) highlighted the trends in antibiotic prescribing and informed the debate around antibiotic usage [4]. GPRD analysis of the increase in proton pump inhibitor prescribing [5] was supported by qualitative studies looking at the drivers for such increases, from the patient and prescriber perspective [6,7]. A further example of the value of this approach using the same database is Frisher's work linking cannabis use to the incidence of psychotic episodes in schizophrenia [8].</p> <p><u>Innovations to enhance prescribing performance: analysis and NHS reports on medicines use and outcomes, advice on the evidence-base, risk sharing and avatars.</u></p> <p>The linkage of primary care data with Hospital Episodes and Statistics (HES) and secondary care data on hospital medicines use (IMS Healthcare) and benchmarking of medicines use and outcomes enabled identification of a number of issues which occur at the interface of primary and secondary care (use of therapy and cost variations), that if addressed appropriately (eg training opportunities, more systematic local guidance) could lead to improved prescribing practice and patient outcomes, alongside cost savings. To enhance the impact of this work, the Keele group established the Midlands Therapeutic Advisory Committee - the first of its kind to consider appropriateness and quality of evidence on behalf of a whole health economy that was the precursor to the National Institute of Clinical Excellence (NICE). A second example of Keele's innovative approach to clinical and cost effectiveness associated with medicines use was the pivotal pilot work on risk sharing of medicines, initially described in the <i>BMJ</i>, in which it was demonstrated how joint working between the NHS and the pharmaceutical industry could increase</p>

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appropriate uptake of medicines, in this case statins for hyperlipidaemia [9,10]. The principle of this approach is an outcomes guarantee in which the drug manufacturers agree to refund the health service if a drug fails to meet agreed performance targets when used under appropriate conditions. Continuing the implementation theme, our work with avatars demonstrate how a virtual environment can be used for clinical simulation in training pharmacists on techniques to influence prescribing and medicines-use behaviours in health professionals and in patients [11].

### 3. References to the research

1. Chapman SR Drug formularies – Good or evil? A View Using Prescribing Analyses and Cost Trends Data. *Cardiology* 1994;85:46–53 doi: 10.1159/000176758
2. Gough A, Chapman SR, Wagstaff K, Emery P, Elias E . Minocycline induced autoimmune hepatitis and systemic lupus erythematosus –like syndrome. *BMJ* 1996 ; 312;169-172
3. Shelley M , Croft P, Chapman SR , Pantin C. Is the practice ratio of inhaled corticosteroid: bronchodilator a good indicator of the quality of asthma prescribing? *BMJ* 1996; 313:1124-1126
4. Frisher M, Norwod J, Bashford J, Millson D, Chapman S Trends in antibiotic prescribing and associated indications in primary care from 1993-1997 *Journal of Public Health Medicine* 2001
5. Bashford J, Chapman S, Norwood J Why are patients prescribed proton pump inhibitors? Retrospective analysis of link between morbidity and prescribing in the General Practice Research Database *BMJ* 1998; 317: 452-456
6. Grime J, Pollock K, Blenkinsopp A Proton pump inhibitors: perspectives of patients and their GPs *British Journal of General Practice* 2001.
7. Boath E H, Blenkinsopp A. The rise and rise of proton pump inhibitor drugs: patients' perspectives *Soc Sci Med* 1997; 45(10)1571-1579
8. Frisher M, Martino O, Crome I, Croft P Assessing the impact of cannabis use on trends in diagnosed schizophrenia in the United Kingdom from 1996 to 2005. *Schizophrenia Res* 113 (2-3) 123-128
9. Chapman S Reeve E Rajaratnam G, Neary R Setting up an outcomes guarantee for pharmaceuticals: a novel approach to risk sharing in primary care *BMJ* 2003;113: 6-7
10. Chapman S Reeve E Price D Rajaratnam G Neary R . Outcomes guarantee for lipid lowering drugs: results from a novel approach to risk sharing in primary care. *Br J Cardiol* 2004;11:205-210
11. Bracegirdle L, Chapman SR (2010) programmable patients: Simulation of Consultation Skills in a Virtual Environment . *Bio-algorithms and Med-Systems* Vol 6 (No 11) pp111-115

### 4. Details of the impact

#### Getting more from PACT

The impact of the Keele University *Centre for Medicines Optimisation* (previously Department of Medicines Management) led by Professor Chapman has been sustained and developed over the last fifteen years. The pioneering work on prescribing analysis reported in *Cardiology* precipitated a service level agreement with the then West Midlands Regional Health Authority and resulted in a series of bespoke annual reports on performance management of prescribing. The then Director of Performance Management, David Lye, stated: “our partnership with Keele has benefited us enormously ...allows us to have constructive and informed dialogue with health authorities and GPs”. These reports set a template for performance management replicated nationally (see exemplar in National Audit Office (NAO) report [1] and, as they have evolved within the changing NHS, continue to do so. [2]

The Keele unit has continued to be commissioned by the NHS and has now produced over a hundred bespoke reports all of whom have their origins in the early papers published by Professor Chapman and his team. Our last report on 'Quality, Innovation, Productivity and Prevention' (QIPP) contains acknowledgement of Keele's impact in the foreword from Claire Howard, national QIPP lead.[1] Our analysis of quality indicators and efficiency measures for prescribing was commissioned for and referenced in the pivotal 'Prescribing Costs in Primary Care' [2]. Quoting the report, Sir John Bourn said “We have found that some small changes in prescribing behaviour can lead to substantial savings for the NHS. All primary care trusts should learn from the best performing PCTs and strive to be as efficient in their own prescribing, making the £200 million in savings realistically achievable”. Indicators of best practice contained in the Keele bespoke reports

(e.g. statins) have found their way into the contract negotiations with general practitioners and became part of their pay structure - the Quality Outcomes Framework (QOF). The challenge in the prescribing arena is definitively proving cause and effect in the maze of variables that affect GP prescribing, but it can be clearly shown that those initial NAO recommendations based on Keele findings have led to prescribing change – notably the push to generic simvastatin, also applicable to atorvastatin, with the associated benefits in both cost saving and health gain [3]. These indicators are still used in the Quality Improvement and Productivity (QIPP) targets currently used in primary care medicines management. Many of the principles and analyses arising from our UK work have been applied internationally through consultancy work for the WHO. References to our reports and corroborators in the WHO, who can testament to in-country impact are provided below [4].

#### Innovations to enhance prescribing performance:

Prof Chapman's papers, book chapters and reports all show how prescribing change can be produced using sound data analysis and robust review of clinical trials evidence. This change does not happen by itself and Prof Chapman has pioneered additional novel implementation strategies to be used alongside quality indicators for prescribing. The first was the use of **pharmacists as trained change agents** –later known as prescribing advisers and medicines management leads. The IMPACT initiative first described in his book *Medicines Management* (1998) continued to be commissioned by health authorities, PCGs, PCTs and CCGs as NHS structures changed. The principles have now been adapted widely throughout the NHS and recommended by the NAO report *Influencing Prescribing Cost and Quality Care* [5].

**The Midlands Therapeutics Review & Advisory Committee (MTRAC)**, started by and supported by Keele's analyses, continues to have a significant impact on prescribing practice in the UK. MTRAC reviews are frequently quoted in NHS documents, medicines information organisations and in the National Electronic Library of Medicine (NELM). The early effects of MTRAC on prescribing, based on an independent evaluation by the Kings Fund are quoted in the Royal College of Physicians report below [6]. The website [www.keele.ac.uk/pharmacy/mtrac](http://www.keele.ac.uk/pharmacy/mtrac) receives over 30,000 hits a month nationally and internationally. There are currently 61 MTRAC reviews available in NELM. The recent *Review Of Specialist Pharmacy Services* contains evidence of the impact of MTRAC on prescribing and subsequent patient gains in safety, health benefit and economy. This confidential report is due autumn 2013 – when available corroboration can be provided. The 2013 General Medical Council report "Good practice in prescribing and managing medicines and devices" directly refers to both MTRAC and the **Effective Shared Agreement Toolkit** we have produced to help ensure safe medicines use across the primary/secondary care interface.[7]

**The outcomes guarantee approach:** initially a pilot in one health authority, was rolled-out nationally by Pfizer for a period of four years, and only halted when atorvastatin came off patent. During that period, many more patients were screened and treated for hypercholesterolemia than would have been the case under standard care and the health benefits from that intervention should be sustained for many years. Results from the initial pilot are in the public domain but the statistics on uptake from the national roll-out are held in commercial confidence by Pfizer UK [8]. The paper is cited in policy papers internationally in USA, Canada and Europe, demonstrating how the concept can improve appropriate use of medicines to improve patient care and has gained traction over time. Two recent examples of this approach in the context of expensive medications are given [9,10].

**Avatars to improve prescribing behaviours:** Prof Chapman's recent work on clinical simulation was originally concentrated on undergraduate education of health care professionals and a version has been licensed to Monash University in Australia. Our avatars have recently been used by two national initiatives – a UKCPA and Sanofi Aventis initiative on VTE risk assessment and a NHS Scotland (NES) programme of online CPD training on pharmaceutical care plans. The NES programme is currently rolling out and will be evaluated in the autumn of 2013. The Sanofi Aventis initiative is bound by commercial confidentiality.

#### **5. Sources to corroborate the impact**

1. *Prescribing costs in primary care – a report by the National Audit Office advocating approaches*

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developed by Keele Medicines Management (Hard copies available if web-link fails).

[http://www.nao.org.uk/publications/0607/prescribing\\_costs\\_in\\_primary\\_c.aspx](http://www.nao.org.uk/publications/0607/prescribing_costs_in_primary_c.aspx) and  
<http://www.nao.org.uk/wp-content/uploads/2007/05/0607454.pdf>

2. NICE website - 2012 QIPP Report including shared learning resources:

<http://www.nice.org.uk/usingguidance/sharedlearningimplementingniceguidance/examplesofimplementation/eximpresults.jsp?o=591>

3. Press Release on NAO Savings: more consistent use of clinically effective generic drugs informed by PACT data analysis estimated a saving of £400m in 2008:

[http://www.nao.org.uk/publications/press\\_notice\\_home/0809/prescribing\\_savings\\_in\\_2008.aspx](http://www.nao.org.uk/publications/press_notice_home/0809/prescribing_savings_in_2008.aspx)

and Article in Pulse describing the impact of Atorvastatin coming off patent using modelling developed by the Keele Medicines Management group.

<http://www.pulsetoday.co.uk/gps-set-for-mass-drug-switch-to-atorvastatin-after-analysis-shows-price-could-fall-by-95/13482969.article>

4. International Impact: WHO and international contacts to corroborate:

Programme Assistant, Health Technologies and Pharmaceuticals Division of Health Systems and Public Health, WHO Regional Office for Europe

Incorporation into government policy: Head, WHO Country Office for Bosnia and Herzegovina and Head of WHO Country Office for Montenegro.

WHO work was commissioned by the regional co-ordinator for Europe (now Director at WHO) who can corroborate the quality of documentation, advice provided, and influence on country policy.

5. Communication plan for prescribing advisors developed by the National Audit Office in conjunction with the National Prescribing Centre, the Department of Medicines Management at Keele: 'Influencing Prescribing Cost and Quality in Primary Care':

[http://www.nao.org.uk/wp-content/uploads/2007/05/7484RC\\_Primary\\_Care.pdf](http://www.nao.org.uk/wp-content/uploads/2007/05/7484RC_Primary_Care.pdf)

6. Royal College of physicians report: ISBN number 1 86016 126X. MTRAC is cited in the summary on page 2 and in Appendix 3, page 64.

7. GMC report Good practice in prescribing and managing medicines and devices (2013):

[http://www.gmc-uk.org/guidance/ethical\\_guidance/14316.asp](http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp)

8. Pfizer UK industry contact to obtain commercial insight and corroboration.

9. Example of the impact of risk sharing

Boggild M, Palace J, Barton P, Ben-Shlomo Y, Bregenzer T, Dobson C, Gray R.

Multiple sclerosis risk sharing scheme: two year results of clinical cohort study with historical comparator. *BMJ*. 2009 Dec 2;339:b4677. doi: **10.1136/bmj.b4677**

10. Publication summarising an international meeting referring to the use of risk sharing schemes to improve equity of access to high cost drug treatment:

McCabe C, Bergmann L, Bosanquet N, et al. Biotherapy Development Association. Market and patient access to new oncology products in Europe: a current, multidisciplinary perspective. *Ann Oncol*. 2009 Mar;20(3):403-12. doi: **10.1093/annonc/mdn603**