Institution: Glasgow Caledonian University

Unit of Assessment: Allied Health Professions, Dentistry, Nursing and Pharmacy

Title of case study: Transforming Care for Women with Pelvic Organ Prolapse

1. Summary of the impact (indicative maximum 100 words)

A research programme of multi-centre clinical trials led by Professor Suzanne Hagen has established Pelvic Floor Muscle Training (PFMT) as an effective treatment for women with prolapse. Hagen's team has also successfully developed a Prolapse Symptom Scale and further tested a Prolapse Staging System to improve outcome measurement for women's health physiotherapists in the UK (20% and 15% clinical uptake respectively). The research has informed local, national and international guidelines and changed practice in 48% of UK physiotherapists. The research has also raised awareness of PFMT treatment for prolapse, with 70% of UK physiotherapists reporting an increase in prolapse referrals.

2. Underpinning research (indicative maximum 500 words)

The pelvic organ prolapse research programme was led by Professor Hagen's team at Glasgow Caledonian University (GCU) within the Scottish Government-funded Nursing, Midwifery and Allied Health Professions Research Unit (NMAHP RU) and externally funded between 2000-2011 by research council, medical charity and professional body grants. A portfolio of clinical trials was founded on the team's published and twice updated Cochrane systematic review,[1] and expert contributions to national and international organisations and consultations in the field.

Researchers established three inter-related studies (the POPPY trial,[2,3] the POP-SS development project[4] and the POP-Q reliability study[5]) [Grants (G) 1-3] cited 72 times, which form part of a larger programme of prolapse research, the outputs of which have over 300 citations. A pilot study[2] [G1] into the effectiveness of Pelvic Floor Muscle Training (PFMT) for the treatment of prolapse was undertaken (Hagen, Sinclair; 2003 to 2005), followed by a landmark definitive, international multi-centre trial[3] [G2,3] which attracted a best paper award with a €1,000 prize at an international conference (Hagen, Sinclair, Dickson, Logan; 2007 to 2011). In tandem, the now widely-used Pelvic Organ Prolapse Symptom Score (POP-SS) was developed to measure key prolapse symptoms and evaluated to facilitate its use within the research programme, the wider research community and the clinical field[4] (Hagen, Sinclair; 2003 to 2009). Finally, a novel study of the feasibility and reliability of physiotherapists using the internationally-recommended Pelvic Organ Prolapse Quantification (POP-Q) system of prolapse staging was undertaken[5] [G4]. This stemmed from identifying the limited use of the POP-Q by the physiotherapy profession (the POP-Q was developed and is primarily used by gynaecologists) which was restricting multidisciplinary working in the prolapse field (Hagen, Dall; 2006 to 2007).

Evidence from the pilot and subsequent trial, the largest most rigorous of its kind, confirmed definitively that PFMT is effective in reducing women's symptoms of prolapse and should be offered by healthcare professionals as first-line treatment[2,3]. In addition to the 23 participating UK clinical centres, centres in New Zealand and Australia secured additional grant funding to take part [G3], increasing the generalisability of the findings.

Reliable measurement of prolapse, both symptoms and anatomical severity (the degree of descent of the pelvic organs), is important for clinical practice and research, to quantify the effects of

treatment. Professor Hagen's team developed a clinically-useful prolapse symptom score (the POP-SS) to meet a gap in the prolapse measurement field, and established its reliability, validity and sensitivity to change[4], and the minimal clinically important difference. Additionally further evaluation was undertaken of the existing standardised and recommended prolapse severity staging system, the POP-Q, to widen its use to physiotherapists, the main professional group responsible for delivering PFMT. The POP-Q was shown to be both a feasible and reliable system for physiotherapists to use[5].

Key Researchers

Professor Suzanne Hagen, Deputy Director & Interventions Programme Director, NMAHP RU
Ms Lesley Sinclair, Research Fellow, Urogenital Disorders Programme, NMAHP RU (start date 1/11/03, end date 30/11/07)
Dr Philippa Dall, Senior Research Fellow, School of Health and Life Sciences
Ms Sylvia Dickson, Research Fellow/Clinical Trials Manager, Urogenital Disorders Programme, NMAHP RU
Ms Janet Logan, Research Assistant, Urogenital Disorders Programme, NMAHP RU (start date 10/12/07, end date 6/6/12)

3. References to the research (indicative maximum of six references)

1. Hagen S, Stark D. Conservative prevention and management of pelvic organ prolapse in women. *Cochrane Database of Systematic Reviews* 2011, Issue 12. Art. No.: CD003882. DOI: 10.1002/14651858.CD003882.pub4.
2. Hagen S, Stark D, Glazener C, Sinclair L, Ramsay I. A randomised controlled trial of pelvic floor muscle training for stage I and II pelvic organ prolapse. *International Urogynecology Journal*. 2009; 20: 45-51. DOI 10.1007/s00192-008-0726-4. Available in REF2.
3. Hagen S, Stark D, Glazener C , Dickson S, Barry S, Elders A, Frawley H, Galea M, Logan J, McDonald A, McPherson G, Moore KH, Norrie J, Walker A, Wilson D. Individualised pelvic floor muscle training in women with pelvic organ prolapse: a multicentre randomised controlled trial. The Lancet, Early Online Publication, 28 November 2013. DOI:10.1016/S0140-6736(13)61977-7. Available in REF2.
4. Hagen S, Glazener C, Sinclair L, Stark D, Bugge C. Psychometric properties of the Pelvic Organ Prolapse Symptom Score (POP-SS). *BJOG: an International Journal of Obstetrics and Gynaecology*. 2009; 116: 25-31. DOI: 10.1111/j.1471-0528.2008.01903.x.
5. Stark D, Dall P, Abdel-fattah M, Hagen S. Feasibility, inter- and intra-rater reliability of physiotherapists measuring prolapse using the Pelvic Organ Prolapse Quantification System. *Int Urogynecol J*. 2010;21(6):651-656. DOI 10.1007/s00192-009-1089-1.

Key grants

1. Hagen S: A feasibility study for a RCT of a pelvic floor muscle training intervention for pelvic organ prolapse. Chief Scientist Office (CZH/4/95); 2003-2005; £37,000.
2. Hagen S: A multi-centre randomised controlled trial of a pelvic floor muscle training intervention for women with pelvic organ prolapse. Chief Scientist Office (CZH/4/377); 2007-2011; £310,000.
3. Galea M: Pelvic Organ Prolapse Physiotherapy (POPPY Australia); National Health Medical Research Council (Grant No. 508925); 2008-2010; £160,000.
4. Stark D: Feasibility, inter-rater and intra-rater reliability of physiotherapists measuring prolapse using the pelvic organ prolapse quantification (POP-Q) system; Physiotherapy Research Foundation (PRF/05/3); 2006-2007; £12,000.

4. Details of the impact (indicative maximum 750 words)

Research within NMAHP RU has led to considerable changes in prolapse practice for physiotherapists in the UK and internationally, including the treatment provided and ways in which prolapse and its symptoms are measured. For example, women now receive evidence-based treatment [Source (S) 1,2], and therefore better treatment outcomes. In addition, their condition and symptoms are more reliably measured and their progress with treatment more accurately monitored [S4-6], therefore again resulting in a better overall outcome. Researchers' work in improving measurement of prolapse has increased the rigour of ongoing audits and evaluations, with an impact on the wider clinical community [S4,6,8]. Evidence of impact has been through personal communication with clinical staff, and the results of an online UK survey of women's health physiotherapists' practice carried out in September 2013 (http://acpwh.csp.org.uk/news/2013/09/09/tell-us-about-your-prolapse-practice-survey).

Our research concludes that significant changes in practice have been necessary, specifically, that PFMT should be the first-line treatment for prolapse. Patient services have been directly improved as a result of the research, for example in NHS Tayside which has adopted PFMT as first-line treatment for prolapse through the development of an integrated care pathway [S1]. Here and in other centres (22% in the recent online survey had a prolapse care pathway), women who would previously have had no treatment, pessary or surgery (associated with side-effects and a high prolapse recurrence rate) are now offered PFMT as a conservative treatment option. 70% of UK physiotherapists surveyed reported an increase in their prolapse referrals in the last five years due to increased awareness of PFMT as an effective treatment option [S3], and 48% reported changing their practice as a result of our findings.

Copies of the POP-SS tool have been requested for use by clinicians across the UK [S5], and 20% of physiotherapists in our UK survey reported that they used it to monitor patient progress. NHS Greater Glasgow and Clyde has included it in a recent update to their clinical assessment tools [S4]. Since 2012, POP-SS has also been recommended in the Australian guidelines for pessary care in the management of prolapse [S7]. A growing number of NHS evaluations [S4,6], published studies [S8] and ongoing funded studies (e.g. the PROSPECT and VUE randomised controlled trials funded by NIHR HTA, and the ProLong longitudinal cohort funded by Wellbeing of Women) have used this tool for symptom data collection. Following our findings that the POP-Q is reliable for use by physiotherapists, its use has increased: 15% of survey respondents reported using POP-Q to monitor patient progress, and NHS Greater Glasgow and Clyde has now formally introduced the use of the POP-Q in their routine physiotherapy assessments [S10]. As a direct result of the research, there has been a considerable increase in routine use of prolapse outcome measures in UK clinical practice. This is providing practitioners with more accurate information about women's prolapse condition to better inform treatment decisions and improve the services provided.

The prolapse research programme has significantly informed international health policy and guidelines. Following consultations with professional representatives, the WHO International Consultation on Incontinence expert committee functions to promote improvements in the management of incontinence and prolapse worldwide through evidence-based recommendations. Recommendations must be suitable for use in all parts of the world, recognising that the health services' resources differ widely between countries. The resulting clinical manual is updated every four years and is vital to clinicians in the field of incontinence and prolapse, providing algorithms to guide practice. Professor Hagen has been an expert committee member on the 3rd, 4th and 5th editions of the manual. The publication includes findings from the Unit's underpinning research

studies and the broader programme of prolapse research, facilitating reach to a worldwide audience of practitioners. It is available via the European Association of Urology and International Consultation on Urological Disease (http://www.icud.info/incontinence.html) websites. Initial distribution of the 5th edition has been to 5,000 clinicians from over 200 countries, including all the member states of the United Nations.

Further research relating to PFMT as a preventative intervention for prolapse has been funded (Wellbeing of Women): PREVPROL, a trial of the effectiveness of PFMT for the prevention of prolapse with two-year follow-up, will complete in December 2013. The expertise in trials relating to PFMT has contributed to the successful funding of a further multicentre trial, the OPAL trial, extending the model to women with urinary incontinence. (£1,970,000, NIHR HTA).

5. Sources to corroborate the impact (indicative maximum of 10 references)

1. NHS Tayside: PFMT for prolapse has been introduced as part of an integrated care pathway (Advanced Physiotherapy Practitioner, Continence, NHS Tayside, January 2012).
2. International requests for trial data/evidence (UK, US, Australia, Brazil, Egypt, Netherlands, Portugal, Israel and South Africa – emails can be provided), and from women suffering with prolapse (UK and US) (April 2007 – present).
3. Online sources where the trial findings have been disseminated:
http://www.hab-it.com/blog/how-effective-is-pelvic-floor-exercise-for-prolapse/
http://www.evidence.nhs.uk/search?q=pelvic%20prolapse
http://www.betterbladders.com/blog/exercising-pelvic-floor-muscles-improves-prolapse-symptoms

4. NHS Greater Glasgow and Clyde: POP-SS used in an audit of practice presented at the Scottish Pelvic Floor Network and joint Malaysian/Scottish urology conference, Kuala Lumpur (Specialist Physiotherapist in Pelvic Floor Dysfunction, June and November 2012).
5. Other specific UK NHS sites known to be using POP-SS routinely: West Suffolk (Senior Physiotherapist, May 2012), Chesterfield Royal (Lead Senior Physiotherapist, September 2010), Nottingham University Hospitals NHS Trust (Senior Women's Health Physiotherapist, October 2012), Southport and Ormskirk Hospital NHS Trust (Specialist Urogynaecology Physiotherapist, March 2013).
6. National pilot scheme evaluation (Chartered Society of Physiotherapists): physiotherapy self-referral pilot scheme for women with prolapse or incontinence in seven geographically spread English (March 2011 to February 2012). http://www.csp.org.uk/publications/project-evaluate-patient-self-referral-women%E2%80%99s-health-physiotherapy-pilot-sites.
7. Australian pessary guideline recommends use of the POP-SS: http://www.unisa.edu.au/global/health%20sciences/sansom/documents/icahe/the%20pessary%20guideline_18%207%202012.pdf (July 2012)
8. Use of the POP-SS in two independent published research studies (Madhuvrata 2011, DOI: 10.3109/01443615.2011.576282; Kashyap 2013, http://dx.doi.org/10.1016/j.ijgo.2012.11.012). Also currently being used at Spire Southampton Hospital (Consultant Urogynaecologist, August 2013).
9. The POP-SS research study was highlighted in the following article in Women's Health Weekly: http://www.highbeam.com/doc/1G1-192777087.html (January 2009).
10. NHS Greater Glasgow and Clyde assessment protocol: the POP-Q is included in pelvic floor assessment protocol and in routine physiotherapy practice (Continence Physiotherapy Clinical Effectiveness Group for the West of Scotland, September 2012).