Institution:
Glasgow Caledonian University (GCU)

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

Title of case study:
Improving the management of pelvic organ prolapse through effective treatment and monitoring: international impact on policy, healthcare professionals and outcomes for women

Period when the underpinning research was undertaken:
2003 to 2019

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Suzanne Hagen	Professor	1996 - present
Marissa Collins	Research Fellow	2011 - present
Philippa Dall	Research Fellow	2005 - present
Sylvia Dickson	Research Fellow	2004 - present
Andrew Elders	Research Fellow	2014 - present
Linda Fenocchi	PhD student	2017 - present
Janet Logan	Research Assistant	2007 - 2012
Helen Mason	Professor	2011 - present
Doreen McClurg	Professor	2008 - present
Nicole Sergenson	Research Assistant	2013 - 2019
Lesley Sinclair	Research Fellow	2004 - 2008
Diane Stark	Secondee, physiotherapist	2010 - 2012

Period when the claimed impact occurred:
1st August 2013 - 31st July 2020

Is this case study continued from a case study submitted in 2014?
Yes

1. Summary of the impact

Suzanne Hagen and team demonstrated that pelvic floor muscle training (PFMT) is effective and cost-effective for prevention and treatment of prolapse, and reduces uptake of subsequent treatment, leading to recommendation of PFMT by NICE, and globally by the International Consultation on Incontinence, who recommend it as first-line treatment. Their discovery of new models of effectively delivering PFMT has provided ways to treat more women than previously possible. Their development, evaluation and translation of the Pelvic Organ Prolapse Symptom Score has resulted in improvements in prolapse care and outcomes in the UK, Australia, Ireland, USA, Ethiopia, India, Brazil, Nepal and Turkey.

2. Underpinning research

Using psychometric evaluation, systematic reviewing, randomised trial and implementation science methodology, Prof Hagen and team undertook ground-breaking research investigating: whether PFMT, traditionally used to treat urinary incontinence, is effective and cost-effective for treating prolapse and for preventing progression of early prolapse symptoms; whether it can be implemented effectively outside a trial context, in the NHS; and whether a brief validated symptom score can be used as part of prolapse management to enhance treatment delivery and outcome.

<u>Providing trial evidence for PFMT for prolapse</u>

Motivated by the lack of any research on the benefits or otherwise of PFMT as a treatment for prolapse, from 2003 to 2011, Hagen and team (DS, AE, SD, JL, LS) carried out a landmark pilot randomised controlled trial (RCT) [G1]. The GCU team then secured £210K from Scottish Government for a definitive full-scale RCT across 25 centre (23 UK, 1 New Zealand, 1 Australian) [G2] evaluating PFMT for the treatment of prolapse which showed that PFMT was effective and cost-effective in reducing women's prolapse symptoms and the uptake of further treatment [R1,R2]. A further award-winning collaborative RCT led by Prof Hagen (with AE, SD, NS, MC) with centres in New Zealand (Prof Don Wilson), Scotland (Prof Glazener) and England (Prof MacArthur) [G3] was funded by Wellbeing of Women (£148K) from 2010 to 2013 involving women with early signs of prolapse, and found PFMT to be effective and cost-effective for secondary prevention of prolapse symptoms [R3]. The resultant Lancet publications in 2014 and 2017 have become primary references for guiding prolapse care.

Implementing trial evidence nationally

To facilitate uptake of their RCT findings within the UK NHS, Prof Maxwell, Univ of Stirling, and Prof Hagen, and her GCU team (DM, AE, HM, LF), undertook from 2016 to 2019 a multicentre implementation study [G4]. This NIHR-funded (£500K) research including a realist evaluation, an outcome study of three different NHS models of PFMT delivery (involving different staff mixes), and a record linkage study of the long-term outcomes of participants in the previous treatment trial [G2]. Findings showed it is possible to train different non-specialist staff to deliver PFMT effectively, and women's self-reported outcomes significantly improved across all delivery models; additionally, PFMT reduced the long-term risk of previous trial participants requiring hospital treatment for pelvic floor disorders, over a post-intervention period of more than 10 years [R4].

Improving prolapse symptom measurement internationally

Having accurate information about women's symptoms is important in order to inform treatment decision-making, and to monitor the effects of treatment. The lack of a brief, reliable and valid measure of prolapse symptoms led Prof Hagen and team (LS, PD, AE) from 2003 to 2016 to develop, test and implement the Pelvic Organ Prolapse Symptom Score (POP-SS) [R5]. This tool can be used by healthcare professionals and researchers working in the field of prolapse, and by women themselves. Its use was reported by 23% of pelvic floor physiotherapists in a UK 2013 survey [R6] and by healthcare professionals and researchers in 12 countries in a 2020 international survey.

3. References to the research

The research comprises the first multicentre trials of PFMT for prolapse [G1,G2,G3], providing evidence previously lacking about effectiveness and cost-effectiveness to inform international guidelines and practice. This was recognised by prizes from the International Continence Society and top 3 BMJ paper status of manuscripts published in the Lancet [R1,R2,R3]. It also includes a novel and comprehensive implementation study funded by NIHR Dept. of Health England [G4] which moved the trial evidence into the NHS and contributed to policy change [R4]. In addition, the first brief validated symptom score for prolapse was developed, which has evidence of high utility for clinical practice globally [R5,R6].

Publications

- R1. Hagen S, Stark D, Glazener C, Sinclair L, Ramsay I. A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse. International Urogynecology Journal. 2009 Jan 1;20(1):45-51: cited 138 times (Google Scholar). https://doi.org/10.1007/s00192-008-0726-4

- R2. Hagen S, Stark D, Glazener C, Dickson S, Barry S, Elders A, Frawley H, Galea MP, Logan J, McDonald A, McPherson G. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial. The Lancet. 2014 Mar 1;383(9919):796-806; cited 225 times (Google Scholar), BMJ top 3

Best UK Research Papers 2015, International Continence Society Best Clinical Abstract 2011. https://doi.org/10.1016/S0140-6736(13)61977-7

- R3. Hagen S, Glazener C, McClurg D, Macarthur C, Elders A, Herbison P, Wilson D, Toozs-Hobson P, Hemming C, Hay-Smith J, Collins M. Pelvic floor muscle training for secondary prevention of pelvic organ prolapse (PREVPROL): a multicentre randomised controlled trial. The Lancet. 2017 Jan 28;389(10067):393-402; cited 58 times (Google Scholar), International Continence Society Best Clinical Abstract 2014, Scottish NMAHP Research Best Paper Award 2017. https://doi.org/10.1016/S0140-6736(16)32109-2

- R4. Maxwell, M., Berry, K., Wane, S., Hagen, S., McClurg, D., Duncan, E., Abhyankar, P., Elders, A., Best, C., Wilkinson, J., Mason, H., Fennochi, L., Calveley, E., Guerrero, K., Tincello, D. Pelvic floor muscle training for women with pelvic organ prolapse: the PROPEL realist evaluation. NIHR Health Services and Delivery Research. 2020 Dec 8:47. https://doi.org/10.3310/hsdr08470

- R5. Hagen S, Glazener C, Sinclair L, Stark D, Bugge C. Psychometric properties of the pelvic organ prolapse symptom score. BJOG: an International Journal of Obstetrics & Gynaecology. 2009 Jan;116(1):25-31; cited 60 times (Google Scholar). https://doi.org/10.1111/j.1471-0528.2008.01903.x

- R6. Hagen S, Stark D, Dougall I. A survey of prolapse practice in UK women's health physiotherapists: what has changed in the last decade?. International Urogynecology Journal. 2016 Apr 1;27(4):579-85; cited 14 times (Google Scholar). https://doi.org/10.1007/s00192-015-2864-9

Grants

- G1. Hagen S, Stark D, Ramsay I, Glazener C. A feasibility study for a RCT of a pelvic floor muscle training intervention for pelvic organ prolapse; funder: Chief Scientist Office; sponsor: Glasgow Caledonian University; duration: 2003-2005; value: £37K

- G2. Hagen S, Stark D, Glazener C, Sinclair L, Norrie J, Wilson D. A multi-centre randomised controlled trial of a pelvic floor muscle training intervention for women with pelvic organ prolapse (POPPY); funder: Chief Scientist Office; sponsor: Glasgow Caledonian University; duration: 2007-2011; 2007-2011; value: £210K

- G3. Hagen S, Glazener C, McClurg, Bain C, MacArthur C, Toozs-Hobson P, Wilson PD, Herbison P, Hay-Smith J. Multicentre Randomised Controlled Trial of Pelvic Floor Muscle Training to Prevent Pelvic Organ Prolapse in Women (PREVPROL); funder: Wellbeing of Women; sponsor: Glasgow Caledonian University; duration: 2010-2013; value: £148K

- G4. Maxwell M, Hagen S (co-CI) et al. Implementation of an evidence-based pelvic floor muscle training intervention for women with pelvic organ prolapse (PROlapse and PFMT: implementing Evidence Locally - PROPEL); funder: NIHR HSDR; sponsor: University of Stirling; duration: 2016-2019; value: £500K

4. Details of the impact

UK and International prolapse policy impact

Five to 10% of women will experience symptomatic prolapse during their lifetime. Two decades ago evidence of effectiveness of PFMT as a treatment for prolapse was lacking, practice varied and no national guidance existed. Since then, guidance recommending PFMT as first-line treatment for prolapse, resulting from our research, was incorporated into the 2013 and 2017 International Consultation on Incontinence reviews [S1]. In 2016 our research was adopted by the German, Swiss and Austrian Societies of Gynaecology and Obstetrics [S2]. Subsequently, NICE in 2019 [S3] incorporated the research results [R1-R3] into their prolapse management

guidelines. The implementation of these guidelines means that PFMT should be offered to improve outcomes for women with prolapse. Drawing on the research [G1-G3], the Pelvic Obstetric and Gynaecological Physiotherapy (POGP) network of the Chartered Society of Physiotherapists commenced prolapse courses in 2014, teaching physiotherapists to deliver PFMT (18 courses, 450 participants) [S4]. The POGP Chair said "The findings of the trials have enabled evidence-based practice to be taught on the POGP prolapse courses, which started in 2014. The findings from the studies have enhanced the teaching content with robust evidence-based research" [S4]. The POGP also developed a patient information leaflet in 2016 including instruction in PFMT, based on the research, and to date have distributed this to around 50 UK care settings to share with prolapse patients [S5].

Following the halt in September 2018 of the use of transvaginal mesh in prolapse surgery, our research was influential in Scottish Government decision-making on physiotherapy provision for women with prolapse. Prof Hagen presented evidence of the benefits of PFMT [G1-G4] from December 2018 - February 2019 to the Minister for Public Health Sport and Wellbeing, and the lead Consultant in Public Health Medicine who stated "I think finding ways this work is reflected in any developing pathways/other areas is vital" (emails available). This led to a presentation in April 2019 to the Scottish Government-appointed Transvaginal Mesh Implants Oversight Group who recommended a need to "undertake a detailed scoping of [physiotherapy] capacity, including referral rates and sources, to determine current needs and future workforce requirements" [S6, page 27].

Influencing professional awareness of the benefits of PFMT in the UK

Delivery of PFMT is challenged by the large numbers of women with prolapse and the limited number of specialist physiotherapists who traditionally deliver PFMT: the UK has only around 800 such specialists. Finding alternative ways to make this evidence-based intervention more widely available were identified in the PROPEL study [G4]. Events to disseminate its findings in London and Glasgow (12/19 February 2019, materials available), were attended by 120 UK clinicians and service managers [R4]. On learning that different models of PFMT delivery, involving non-specialist staff, were effective and acceptable, participants shared action plans to implement changes to their services (transcripts available). Action plans contained statements such as: "I have some good ideas and emerging evidence to take to the commissioners"; "[I] feel enthusiastic and determined to participate in providing this effective treatment, improve pathways, developing information leaflets for patients/women". Implementation of such models allows a wider group of existing staff to treat women, giving better access to PFMT, and freeing up specialist teams for complex prolapse cases. This argument was presented to an Oral Hearing of the Independent Medicines and Medical Devices Safety Review of vaginal mesh by the Chartered Society of Physiotherapists who emphasised the importance of the PROPEL findings [G5] in increasing the workforce for PFMT delivery [S7, page 90].

International clinical practice and patient impact

Clinicians treating women worldwide, recognising the need for a brief validated prolapse symptom score, have adopted the POP-SS, developed and validated by Prof Hagen [R5-R7], and the instrument has been translated into Amharic, Turkish, Nepalese, Chinese, Russian and Samoan (publications and emails available). In Nepal this facilitated research into PFMT delivery during pregnancy [S8]. According to a 2020 survey of POP-SS users [S9], with respondents from the UK, Australia, Republic of Ireland, USA, and countries where there is a significant unmet clinical need such as Ethiopia, India, Brazil, Nepal and Turkey, the respondents used the POP-SS to monitor women's prolapse symptoms (89%), and to share information with patients (78%) and colleagues (60%). Over 70% included the POP-SS within their patient records. For 40%, the POP-SS was used to inform treatment decisions, e.g. whether or not to proceed to surgery. Respondents reported it improved their clinical practice (73%), and treatment outcome (42%), specifically it "allowed management to be more appropriate" and led to "quicker resolution of issues".

5. Sources to corroborate the impact

- S1. Title: International Consultation on Incontinence book, Chapter 12 Adult Conservative Management, reviewing evidence on PFMT as a treatment for prolapse (p 1547, 1549, 1575), treatment algorithms p 2577-2578. Date: 2017. Link: https://www.ics.org/education/icspublications/icibooks

- S2. Title: Diagnosis and therapy of female pelvic organ prolapse. Guideline of the DGGG, SGGG and OEGGG (S2e-Level, AWMF Registry Number 015/006, April 2016). Geburtsh Frauenheilk 2016; 76: 1287–1301) Page 1292, 1298. Date: April 2016. Link: https://boris.unibe.ch/94553/1/s-0042-119648.pdf

- S3. Title: National Institute for Health and Care Excellence (2019) Urinary incontinence and pelvic organ prolapse in women: management (NICE guideline NG123). Page 17-39. Date: April 2019. Link: https://www.nice.org.uk/guidance/ng123/evidence/evidence-review-h-lifestyle-and-conservative-management-options-for-pelvic-organ-prolapse-pdf-6725287413

- S4. Title: Testimonial from the Chair of the Pelvic Obstetric and Gynaecological Physiotherapy network of the Chartered Society of Physiotherapists. Date: May 2020

- S5. Title: Pelvic Organ Prolapse – a guide for women including the POP-SS. Date: 2016. Link: https://pogp.csp.org.uk/system/files/pogp-prolapse.pdf

- S6. Title: Transvaginal Mesh Implants Oversight Group Final Report (Page 27). Date: April 2020.
Link:http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/programme_resources/transvaginal_mesh_implants/tvmo_final_report.aspx

- S7. Title: Evidence from PROPEL study provided to the Independent Medicines and Medical Devices Safety Review of vaginal mesh (Page 90). Date: May 2019.
Link:https://www.immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20-%20Evidence%20Submitted%20Following%20Oral%20Hearings.pdf

- S8. Title: Use of the Nepalese POP-SS in Acharya RS, Tveter AT, Grotle M, Khadgi B, Braekken IH, Stuge B. Pelvic floor muscle training programme in pregnant Nepalese women—a feasibility study. International Urogynecology Journal. 2019 Jul 25:1-1. Date: 2020. Link: https://link.springer.com/article/10.1007/s00192-019-04053-1

- S9. Title: Hagen S, Ierna M, Frawley H. International use of the Pelvic Organ Prolapse Symptom Score: results of an online survey. JPOGP in press. Date: November 2020. Link: https://researchonline.gcu.ac.uk/en/publications/international-use-of-the-pelvic-organ-prolapse-symptom-score-pop-