Scottish Stoma Clinical Nurse Specialist Group

Effective Use of Support Garments for Parastomal Hernia
Results of Short Life Working Group

June 2019

Contents

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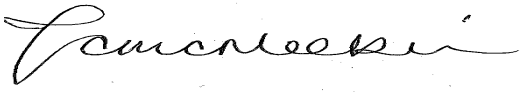
Approved by : Date Signature	Scottish Stoma Nurse Group Chair on behalf of SSNG 22.01.2018 
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Revision History

Version	Date	Actions	Lead	Comments
0.1	**14.11.17**	**To embed final agreed nursing pathway & add financial benefits**	**AH/DL/ BH**	
0.2	**12.12.17**	**Final pathway docs submitted**	**AM**	**Pdf updated version embedded**
0.3	**08.01.18**	**Amendments from CNS comments**	**AM/ SLWG**	**Addition of NP reviewed expenditure and financial benefits** **Section 5.9**

1.0 Introduction

1.1 Ostomy accessory products represent a significant proportion of healthcare prescribing expenditure, with a limited evidence base to support clinical use (3,5,8).

Across the UK Ostomy accessory product use is rising. Expenditure in NHS England estimated at circa £70 million per annum and circa **£5.7million** per annum across NHS Scotland.

1.2 Ostomy prescribing optimisation projects across NHS England and NHS Scotland have evidenced inappropriate prescribing and waste associated with unwarranted variation (5,12). Unwarranted variation' refers to the over-use or under use of different aspects of healthcare products and services that cannot be explained by medical need or the dictates of evidenced based practice (6).

1.3 Support garments are a stoma accessory promoted and sold by suppliers as products to prevent and manage parastomal hernia (PSH). These garments are available on prescription and range from lightweight underwear to firm support corsets and belts. Annual NHS Scotland expenditure is circa **>£200,000 per annum** and estimated NHS England expenditure circa >£1.4 million per annum (8).

There is industry promotion of these products for prevention despite a lack of robust evidence that would support the use of these products and inconsistencies in the support criteria of these garments (3).

1.4 This identified an opportunity for The Scottish Stoma Nurse Group (SSNG) to review the quality of PSH care and optimise product use.

1.5 A short life working group (SLWG) was established by Scottish Stoma Nurse Specialist Group (SSNG) in November 2016 to review the current prescribing of support garments for ostomy patients and develop recommendations that would support a Once for Scotland approach of PSH nursing management and offer a pragmatic approach to cost effective prescribing practice of these garments. **(Appendix 1a)**

1.6 Key stakeholders in the group included; representation from Health Board Stoma CNS Services and National Procurement to provide information on garment prescribing costs, volume and variation across NHS Scotland and provide project management to the SLWG.

1.7 Industry trade body collaboration was sought from the British Healthcare Trade Association (BHTA) to review and comment on the process of establishing garment support criteria.

1.8 The SSNG had approached patient groups and discussed the need to review and improve the support garment prescription practice. This was received positively by the majority of patient groups approached.

2.0 Literature Review

2.1 Parastomal hernia (PSH) is a common complication following colostomy, ileostomy and urostomy stoma creation (1-9). It has been defined as an incisional hernia that occurs at or adjacent to the stoma. Reported incidence varies widely ranging from 20% - >50% which are attributed to different methodological approaches across research study populations (1,6,7).

PSH is regarded as a late effect following stoma formation occurring mainly within the first two years after stoma creation (1-9). Many patients with PSH may be asymptomatic, however reported complications include discomfort, increase in appliance leakage with subsequent skin irritation and embarrassment which negatively impacts on quality of life (3,9). A more serious complication is the development of obstruction characterised by acute abdominal pain which requires emergency surgical assessment and intervention (1-7).

2.2 Diagnosis

Diagnosis of PSH is with clinical examination where a swelling is noted in the vicinity of the stoma with the patient straining in erect or supine position.

Classification of size and type of PSH is by direct measurement and or radiological imaging as detailed in table 1 (1, 7,8).

Table 1

Size	**Classification**	
Clinical examination	Radiological Imaging	
Small = below 5 cm	Interstitial	Enters into muscular plane
Medium = 5-10 cm	Subcutaneous	Enters into the subcutaneous tissue
Large = >10cm	Intrastomal	Enters between the emerging intestinal wall and everted intestinal layer
	Peristomal	Enters the space between the layers of prolapsed bowel

2.3 Risk Factors

Patient characteristics are considered the most important risk factor in development of PSH reported across the literature (1,9). The most pertinent include; age, increased BMI >25, increased waist circumference > 100cm, smoking and the presence of co-morbidities such as respiratory disease and diabetes (3-9).

Surgical techniques used in the formation of a stoma such as stoma approach, placement site and size of the stoma opening are thought to be predicative factors in PSH development (1,6,14) however, due to the lack of clinical trials comparing surgical techniques across all ostomy groups, the ideal approach remains controversial (1,6). Varying rates of PSH have been reported across all types of ostomates but rates of PSH development appear higher for colostomy (6, 7).

2.4 Surgical Management

Surgical repair of a PSH is the only curative option. Surgical options for repair may include relocation of stoma, local repair and mesh repair (5-7). These procedures have associated morbidities and a risk of hernia recurrence. It is thought that development of safer biological mesh material may increase the potential of prophylactic surgery to prevent PSH in high risk groups as well as improving the surgical options for patients who develop a PSH (1, 6, 14).

Non surgical management of a developed PSH includes the use of firm support garments that provides support to the hernia and may reduce discomfort. Support garments should be accessed following assessment by a stoma CNS who will offer guidance on the optimal garments and arrange supply and expert fitting. Regular review is advised to monitor PSH symptoms, effect on ostomy function and quality of life (3,8,9).

2.5 Prevention

Nursing research has reported several strategies to prevent PSH that include the importance of pre –operative stoma sitting (3,4,8,9), patient education on PSH development, prevention strategies that include weight management, performing regular core abdominal exercise and the use of a firm support garment in patient who are assessed as high risk for developing PSH(3,8,9).

Although these strategies have been reported to reduce the incidence of PSH it is unknown which strategy is more successful. There is no robust research that supports the role of support garments alone for prevention of PSH as they are used in combination with other prevention strategies.

As part of this SLWG the SSNG approached the Scottish Health Technologies Group; Health Improvement Scotland to conduct an appraisal on the use of support garments for PSH prevention and management. The response was that there was inadequate research published to warrant an appraisal.

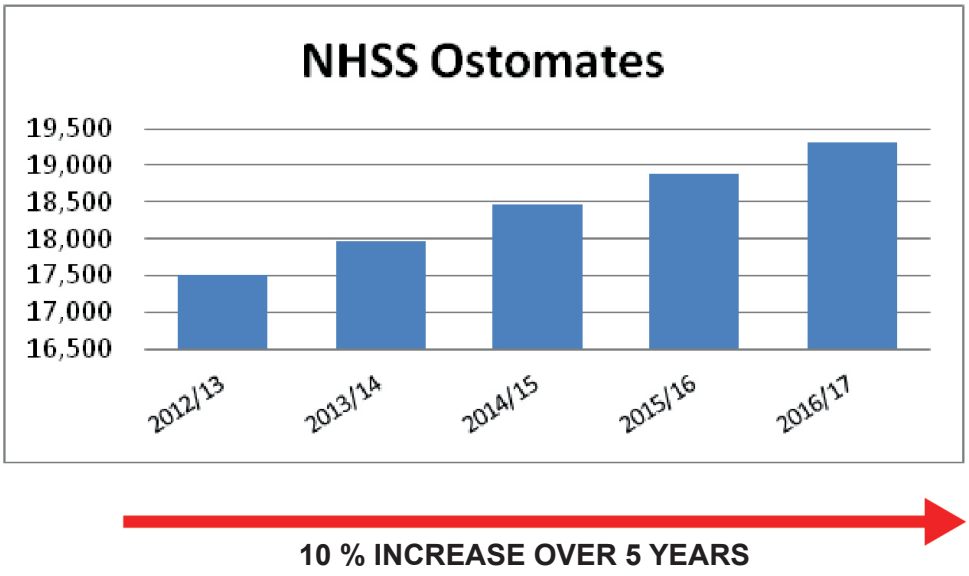
A common theme from published literature on prevention of PSH is that patient concordance is crucial factor in successful prevention of PSH development with poor levels of adherence to weight reduction, exercise; lifestyle modification and regular appropriate wearing of a support garment (3,8,9).

A lack of data to evaluate patient outcomes limits the efficacy of these prevention strategies.

3.0 NHS Scotland Support Garment use and Expenditure

Information from ISD Scotland shows the number of ostomates across NHS Scotland over a five year period. In 2016/17 the number of ostomates was **18,750** with data reporting a 10% increase over 5 years (Fig 1).

Figure 1



3.1 Although the literature reports varied incidence rates of PSH incidence, data across NHS Scotland is limited with no robust historical data.

Information from ISD Scotland reveals that SMRO1 codes to identify PSH incidence has only been collated since April 2017; therefore annual figures for PSH are uncertain.

3.2 Support garment expenditure is primarily in community where complications occur, and prescribing of garments is within the remit of a G.P practice.

3.3 NHSS Garment expenditure in 2016 was circa **£272,780** which is approximately **5%** of the total accessory expenditure in 2016 circa £5,703,882.

3.4 **Table 2** reports NHS Scotland community garment volumes over a 4 year period.

The overall NHS Scotland trend shows an increase in volume since 2012/13 with a decrease in 2016/17 reflecting activity of some health boards to manage product use.

Individual health board analysis however shows 50% of health boards in 2016/17 have an increase in community garment volumes.

Table 2

NHS Scotland Community Garment Volume Identified by ISD under belts					
Health board	**2012/13**	**2014/15**	**2015/16**	**2016/17**	**Trend**
A &A	486	462	481	463	↓
Borders	169	194	205	218	↑
Dumfries & Galloway	119	143	127	123	↑
Fife	500	479	474	467	↓
Forth Valley	267	268	304	230	↓
Grampian	439	497	551	581	↑
GG&C	1443	1600	1742	1815	↑
Highland	433	494	494	463	↓
Lanarkshire	1176	1390	1524	1213	↓
Lothian	1001	1072	1142	1020	↓
Orkney	12	17	19	14	↓
Shetland	35	49	46	56	↑
Tayside	751	780	731	763	↑
Western Isles	26	462	18	11	↓
NHSS Total	**6857**	**7473**	**7858**	**7437**	↓
NHSS Trend	↑	↑	↑	↓	

3.5 **Table 3** reports NHS Scotland support garment expenditure over a 4 year period which corresponds to **table1** volume data with an overall decrease in 2016/17 reflecting activity of some health boards to contain product use.

Health board analysis however shows the 50% of Health boards have an increase in community garment corresponding to increased volumes.

Table3

NHS Scotland Community Garment Expenditure Identified by ISD under belts						
Health board	**2012/13**	**2014/15**	**2015/16**	**2016/17**	**H B Trend**	
A &A	£22,403.89	£23,222.79	£25,452.28	£24,012.17		↓
Borders	£5,452.91	£5,822.18	£6,561.77	£8,392.56		↑
Dumfries & Galloway	£3,982.92	£5,379.56	£4,931.16	£5,542.63		↑
Fife	£13,640.79	£13,908.16	£14,291.36	£13,711.23		↓
Forth Valley	£8,075.47	£9,574.60	£10,871.45	£9,367.92		↓
Grampian	£12,104.32	£13,194.93	£15,352.28	£18,923.71		↑
GG&C	£54,860.05	£61,567.47	£69,074.25	£68,918.89		↑
Highland	£11,102.29	£13,686.65	£14,639.64	£14,313.97		↓
Lanarkshire	£47,083.34	£56,297.49	£62,900.95	£43,562.34		↓
Lothian	£26,899.63	£29,327.57	£34,815.76	£31,246.51		↓
Orkney	£197.37	£314.71	£335.87	£246.02		↓
Shetland	£814.72	£1,298.28	£1,429.76	£2,271.18		↑
Tayside	£18,131.18	£21,760.45	£19,466.75	£20,743.91		↑
Western Isles	£575.05	£865.85	£1,161.88	£470.35		↓
Total	**£225,323.93**	**£256,220.69**	**£281,285.16**	**£261,723.39**		
NHSS Trend	↑	↑	↑	↓		

3.6 Expenditure data compiled by ISD prescription service and National Procurement contains garment information from suppliers. Product descriptions do not clarify the garment support level as currently no national agreed support criteria exists. Therefore it is challenging to identify support garments that would not fit current prescribing guidance.

3.7 The Association of Stoma Clinical Nurse Specialists (ASCN) recently published guidance (3) which advise self purchase of high waited support underwear with lycra for PSH prevention, with prescription of a **higher level** of support garment advised for patients who been assessed with a higher risk factor for PSH development.

3.8 This supported the need to develop a process to identify support garments that would meet an optimal support criteria aligned to guidance for garments that should be prescribed for prevention and management of PSH.

4.0 Survey of NHS Scotland Nursing Management of Parastomal Hernia: Access and prescribing practice for support garments.

4.1 Access to Garments

Ostomy patients are free to choose how their ostomy appliances and accessories are issued.

Access can be via a pharmacy dispensing contractor or via a Dispensing Appliance Contractor (DAC).

A G.P prescription is required to enable dispensing. Across NHSS prescriptions are completed by G.P's who have limited knowledge of these products to question usage or volumes.

Supplier marketing is thought to influence the use of support garments as currently there is limited control or screening processes in place to decide if these products are clinically required.

Variation across Health board practice may also impact on equitable access to support garments, which could impact on patient outcome data.

4.2 A questionnaire was developed to review the current NHS Scotland access and prescribing practice for support garments for prevention and management of PSH. (Appendix 1 b)

The aim of the questionnaire was to identify current NHS Scotland practice of support garment use for a parastomal hernia, current management protocols and prescription practice. There is significant use of support garments across NHS Scotland with various levels of support ranging from light, medium and firm with no clarity on definitions of these levels

The results of the questionnaire would inform development of an equitable practice across NHS Scotland.

4.3 Results

10 Health Board Acute Stoma CNS/ANP services (who were part of the SLWG) completed the questionnaire with stoma nurse colleagues to reflect their HB practice. The questionnaire consisted of 9 questions developed to report on access and prescribing practice for support garments for parastomal hernia.

The response rate was 100% (10 out of 10 Health Boards surveyed responded).

Full results on the questionnaire are detailed in Appendix 1b

4.4 Key points

1. The survey highlights the absence of current nursing management protocol or guidelines for parastomal hernia prevention and management in all NHS Scotland Health Board stoma services.

2. Across all health board there are established stoma nurse led clinics, with all CNS respondents reporting that the stoma nurse led clinic is the main referral point if a patient develops a parastomal hernia.

   Additional referral points include G.P and acute surgical clinic.

3. There is variation in practice across all health boards regarding the support level CNS's would advise for prevention (light, medium and firm support level) and for an established hernia.

4. The current role of the stoma CNS is to assess patients and advise on the appropriate support garment with prescribing of garments under the responsibility of primary care G.P's. However,

there are a variety of health care professionals (n=7) that provide advice if a patient requires a support garment for a parastomal hernia, with variation in practice across all health boards.

5. Stoma CNS's across NHS Scotland are primarily acute based, with limited capacity to provide additional community patient garment review to assess optimal product use, efficacy of garment. **This would require additional resources.**

6. The results provide evidence of variation in practice across NHS Scotland regarding the advice, prescription practice and support levels of support garments for PSH prevention and management.

4.5 Actions

1. The findings of this survey enabled the SLWG to develop NHS Scotland guidance that would support an equitable, evidenced based practice of appropriate support garment prescribing advice, and pathway adapted from the national ASCN PSH guidance. **(Appendix 1 c).**

2. A Support level criteria for garments to be developed in collaboration with BHTA that would aid identification of optimal support garments.

5.0 Support Level Criteria

5.1 The Scottish Stoma listing is a document complied by NHS National Services from supplier information and details products available for prescription.

The current challenges in identifying appropriate support garments from this document include;

1. The section on support garments currently has 27 pages of support products listed under the heading of belts with a vast range of products.

2. Product descriptions range from underwear; pants & vests, waistbands, belts and corsets.

3. There is limited descriptive information from suppliers of the supportive nature of these garments that clearly identifies the level of support.

4. Supplier information contains both descriptive support levels:

   (Light, Medium and Firm) and a numerical support level

   (Level 1, level 2, level3)

5. There is currently no consensus between the descriptive and numerical support criteria and the fibre content that would differentiate support garments enabling clear identification of support levels.

5.2 Compression Hosiery Classification (BNF)

There is a classification for compression hosiery which has a British standard & Lymphoedema garments have a European classification (1 – 4 plus).

"Before elastic hosiery can be dispensed, the quantity (single or pair), article (including accessories), and compression class must be specified by the prescriber. There are different compression values for graduated compression hosiery and lymphoedema garments

All dispensed elastic hosiery articles must state on the packaging that they conform to Drug Tariff technical specification No. 40, for further details see Drug Tariff "(BNF section 5.9 2016)

5.3 The SLWG aimed to develop a process to categorise current support garments in line with BNF descriptions for compression hosiery garments that would enable accurate product guidance.

5.4 **Table 4** details the support criteria guidance drafted by SLWG with the aim of engaging BHTA to assist & guide in this process.

Table 5 details amendments made by BHTA which details support level as 1 and 2 with descriptions for each level.

Table 4

Company	Add Supplier name here		
Category	Supplier to input details (i.e. pants, vest, belt, etc.)		
Product	Supplier to input details (add once only if same product with different sizes and colours)		
Support Level	Level 1	Level 2	Level 3
Support Rating	Light	Medium	Firm
Description to match support level			
Fibre Content for support level rating			

Table 5

Support Level	1	2
Support Rating	Stoma Support Device	Abdominal and Stoma Support Device
Description to match support level	A loosely woven device, which provides support to the Stoma and covers the bag. It should be high waisted (belt or underwear) and with or without an internal pocket system. Supervision of a healthcare professional or professional fitter is not required.	A tightly woven device, which offers support to the abdominal wall, the stoma and the stoma appliance by reducing the movement of the abdominal wall, counter acts increased abdominal pressure and thereby promotes adherence. **It may prevent hernia occurrence as shown in studies for prevention and management of parastomal hernias.** The number of items required per patient per year would be relevant to the individuals wear time and it is suggested these devices, support girdles or belts should only be used under the supervision of a healthcare professional or professional fitter.
Fibre Content for support level rating	Latex free	Latex free

5.5 The SLWG accepted the amended support criteria (Table 5) from the BHTA who through National Procurement were asked to contact garment suppliers to populate a spreadsheet with their garments.

A spreadsheet detailed supplier feedback with garments identified by the industry as Level 1 and garments as level 2.

5.6 Stoma CNS representatives on the SLWG reviewed this information with their health board colleagues to confirm Level 1 & 2 garments identified by the industry. There was initial variation from health board's response which necessitated a more detailed review of the industry response by CNS SLWG to reach consensus and agree garment support levels. Garments that were included by industry and identified by SLWG as no support garment remain available for prescription.

5.7 The final review from CNS SLWG identified garments that fit Level 1 and 2 with consensus reached that;

- Level 1 garment should not be prescribed and could be self purchased from high street stores **(Appendix 1 d)**.
- Level 2 garment was identified as suitable for prescription to offer a greater support level for prevention in combination with weight management and core abdominal exercise programme in high risk patients following Stoma CNS assessment.
- Level 2 garment would be advised to offer support for an established PSH following Stoma CNS assessment **(Appendix 1 d)**.

5.8 It is important that NHS Scotland PSH pathway is followed with the need to monitor PSH prevention and management strategies with collation of patient outcome data. This will provide key information that will inform a model of care delivery aligned to NHS Scotland quality dimensions of; Safe, Timely, Effective, Efficient, Equitable and Person centred ostomy care delivery.

5.9 **Projected Financial Benefit** in Table 6 taken from Prism data from Level 1 & 2 garments.

Table 6

Total NHSS Garment Expenditure (2016/17) prior to garment review	£272,780.00
Following this review: Annual Value of Level 1 Garments (Oct 16 -Sep 17)	£80,002.36
Annual Value of Level 2 (Oct 16 - Sep 17) New Core List Support Garments for Prescription	£165,452.69
Projected savings (Total NHSS 2016/17 cost - Level 2 = £27,325 + L1£80.002 = £107,327	£107,327.31

6.0 Recommendations

Following development of a categorisation process in partnership with industry the group have developed a process where there is improved clarity of garment support levels. Following this process the group recommend the following:

1. Level 1 garments for self purchase & not for prescription.
2. All patients following stoma surgery will be advised to wear a support garment either Level 1 or Level 2.
3. Level 2 garments are suitable for prescription for PSH Prevention and Management following a Stoma CNS risk assessment review and Level 2 garment advice.

4. Any new garments submitted to National Procurement for prescription will require to be categorised as level 2 with evidence to support this & approved by SSNG

5. Garments prescribed by community G.P or nurse prescriber must be identified as Level 2 and prescribed only on advice from stoma CNS following patient review using the developed NHS Scotland PSH pathway including use of risk assessment, QoL, patient lifestyle education, exercise guidance and outcome evaluation.

6. DACs or industry not to advise patients to seek prescription of garments from G.P without clinical review by stoma CNS to confirm requirements for a Level 2 garment

7. Identify resources to support Health Board patient review and audit of support garments.

8. Identify the process to implement the revised Level 1 & 2 garments across NHSScotland.

9. Analytical support should be sought to collate the findings from CNS PSH assessment and risk factor proforma to enable outcome monitoring with the ability to benchmark patient outcome data across NHSScotland.

Actions

1 Identify an appropriate leadership body to develop an action plan take these recommendations forward within a suggested timeline of March 2018.

2 The Evadis team in ISD would be the appropriate body to advise on administrative process for implementation of the new garment Levels.

3 Develop and agree communication strategy to key stakeholder and patient groups when the report is ratified.

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Membership of Support Garment Short Life Working Group

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Appendices

Appendix 1a:Terms of Reference

Scottish Stoma Nurse Specialist Group Terms of Reference

Appendix 1b: NHS Scotland Parastomal Hernia Nurse Management Questionnaire

PSH Questionnaire

Appendix 1c: PSH NHSS Nursing Pathway

PSH Pathway risk assessment
PSH Management NHSS
PSH Prevention NHSS

Appendix 1d: SLWG Revised Level 2 Garments:

PSH Level 1 Garments
PSH Level 2 Garments
L1 L2 Garments worksheet