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Terms of Reference:

a. National Stoma Quality Improvement Short Life Working Group
b. NHS Scotland Stoma Fora Survey Report
c. NHS Scotland Stoma Fora Briefing Paper
d. NHS Scotland Prescribing Guidance

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Executive Summary

The National Stoma Quality Improvement Short Life Working Group (NSQIG) was commissioned by the NHS Scotland Executive Nurse Director Group (SEND) and established in February 2018. The Scottish Deputy Nurse Director Group (SDNDF) nominated a chair and vice chair to provide governance and leadership to the work of NSQIG. The work of the group was fully supported by National Procurement (NP) Senior Nurse and management personnel from National Services Scotland (NSS).

NSQIG membership includes regional Stoma Nurse representation, Health Board prescribing support, pharmacy, G.P representatives, Colorectal Surgeon, procurement and prescribing analyst support. Wider engagement was established with Directors of Pharmacy, Health Board Stoma Fora and commercial partners.

NSQIG adopted a values-based approach to identify how stoma care is optimised by delivering the best possible patient outcomes in the most efficient way to ensure resources are allocated for maximum clinical and financial value.

This report contains references to Information Services Division (ISD). ISD formed part of NHS National Services Scotland (NSS) until April 2020, when it joined the new Public Health Scotland body.

Rationale for establishing National Stoma Quality Improvement SLWG (NSQIG)

1. The Stoma care service affects a large number of service users across the United Kingdom (UK). It is also an area of care with evidence of increasing expenditure with over ordering, variation in product use and patient outcome monitoring frequently identified in primary care. This has significant clinical and financial impact (1,3).

2. Across the UK, over £260 million is spent annually on stoma products. Stoma appliances and accessory costs in primary care can range from £780–£2,300 per patient per annum. In situations where there is inappropriate product use, the cost can rise above £6000 per annum (1,2,30).

3. Primary care stoma expenditure in NHS Scotland has risen by 65% over five years with a current expenditure of £31 million per annum. In contrast, stoma patient numbers have increased by 10% over the same period.

4. The NHS Scotland Stoma Care Quality and Cost Effectiveness Review (2016) identified that all areas of ostomy product use were in excess of established guidelines; identifying waste and variation (3).

5. Evidence from the literature indicates that increasing appliance and accessory use is often linked to stoma complications or adverse events such as leakage and skin complications, which negatively affect a patient’s quality of life (16,17,19).

6. Stoma efficiency and enhancement projects have demonstrated that by improving the quality of stoma care by more effective prescribing and appliance selection, more responsive patient monitoring and minimising variation in practice, a reduction of up to 20% in stoma expenditure can be delivered by reducing wastage, improving self-management and patient outcomes (1).

7. The product range is subject to considerable commercial marketing since stoma products and accessories can be directly promoted to the targeted audience. The ready availability of samples through online websites and publications can influence patients to request products to be added to prescriptions with no prior clinical assessment of need.

8. Many of these product requests have not involved a Stoma Nurse; the clinical nurse specialist with considerable knowledge and expertise on the use and effectiveness of stoma products who, in most cases, will be unaware that such an item has been requested via this route.

The aim of NSQIG is to identify, prioritise and progress areas of work requiring a national “Once for Scotland” approach, complementing NHS Boards stoma quality and efficiency activities aligned to the stoma quality and cost effectiveness national review (2016).

This report draws on the findings and recommendations from the National Stoma Quality Improvement Short Life Working Group (NSQIG).

Key Messages

- Concern exists that under and over use of stoma products as a result of problems related to stoma care or morbidity, largely occurs as an un-detected clinical event across Scotland. It is known that stoma related morbidity such as leakage and skin complications will negatively impact on the quality of life for stoma patients.

- Improvements in patient monitoring, assessment of product effectiveness and efficiency of stoma prescribing will support effective product use. These will also improve quality of life by early identification and management to minimise stoma-related associated morbidity. This will also support reduction of waste and unwarranted variation associated with inappropriate product use.

- Recognition and reduction of unwarranted variation and waste was therefore an overarching theme from the work of NSQIG, which is supported by key health and social care strategic policies.

- There is evidence of a distinct gap in the format and reporting of stoma prescribing data across NHS Scotland Boards which is a compounding factor.

- The NSQIG Data Subgroup developed a series of metrics to guide NHS Health Board on product use and cost per treated patient variation across a number of metrics, with benchmarking across all NHS Boards against national prescribing guidance which narrows this gap.

- NHS Scotland Stoma Care prescribing guidance has been developed as a pragmatic decision-making aid to support more effective product use and to reduce variation.

- Reliance on General Practitioner stoma prescribing has been noted as both a workload issue in primary care and a contributory factor in prescribing variation of stoma products and accessories.

- Alternative models to GP prescribing require proof of concept testing to fully evaluate how a non-medical prescriber or non-prescription based approach could better utilise existing resources within the multi-disciplinary team and improve patient outcomes.

- Stoma Nurses continue to play a critical role in the delivery of specialist stoma care and in the support and advice given to wider professionals. However, there is a noted lack of consistency in how Stoma Nurse roles are supported and deployed across Scotland, creating variation in how patients and colleagues can access this expertise.

- Implementation of the recommendations from the NHS Scotland Stoma Care Quality and Cost Effectiveness Review (2016) across NHS Boards appears to be patchy with particular reference to patient feedback, quality monitoring and the establishment of Stoma Fora and recognised Board Leads.

- There is a need for more integrated leadership across the nursing and pharmacy professions both locally and nationally.
Recommendations

1. NHS Boards who currently do not have an established Stoma Forum should consider this in line with the recommendations from the NHS Scotland Stoma Care Quality and Cost Effectiveness Review (2016).

2. SEND to consider development of a national approach to support the development of a national stoma care minimum data set, aligned to the established Excellence in Care (EiC) assurance measures, enabled by digital solutions, to improve monitoring of patient outcomes. This will aim to reduce current reliance on use of industry data software by NHS Board-employed healthcare professionals.

3. For resource requirements to be identified that would support the delivery of strategic level stoma product prescribing data reports to all territorial Boards, supporting the scrutiny and monitoring arrangements across prescribing and clinical teams.

4. National prescribing guidance developed by NSQIG should be adopted across NHS Scotland to support NHS Board’s equity of practice and facilitate improved prescribing practice. Dispensing Contractors should be informed of the process, contained within prescribing guidance for reporting stoma related adverse events within a clinical escalation pathway.

5. National Procurement (NP) to review and strengthen how it works with NHS Boards to provide improved governance, transparency and professional accountability in the commercial Value for Money (VM) review process.

6. SEND to remit SDNDG to review the leadership, reporting and accountability arrangements with the Scottish Stoma Nurse Group in order to strengthen the professional governance and strategic work of this group.

7. Primary Care Teams within NHS Boards to actively consider the use of serial prescribing within the Managed Care & Review service, supported by Primary Care Pharmacists and Stoma Nurses, to improve monitoring, effectiveness and efficiency of stoma prescribing.

8. Scottish Stoma Care Nurse Group to develop stoma care quality assurance measures, aligned to Excellence in Care (EiC) methodology. Quality assurance measures should cover early detection and management of stoma related adverse events. An integrated approach should involve the wider primary care team and provide clear clinical escalation pathways to specialist advice and intervention.

9. That NHS Boards support Stoma Nurses to consider wider use of Technology Enabled Care such as Florence to support self-management, monitoring and outcome measurement.

10. SEND / DoP’s to consider Proof of Concept evaluation of alternative models to stoma appliance and accessory product prescribing to see if improved patient outcomes and more effective and efficient product use can be achieved.

11. NHS Boards to review future Stoma Nurse workforce requirements in line with CNOD Transforming Roles Programme and the findings of this review.

12. Scope how NES can work with Scottish Stoma Nurse Forum to develop a framework of post graduate educational and clinical preparation requirements for stoma care nurses in line with the NES Career Development Framework and CNOD Transforming Roles Programme. This should include a review of the current industry supported education and CPD provision.

13. SEND to consider continuing the work of NSQIG in the form of a national leadership group to progress the recommendations contained in this report as Phase 2 of this work.

14. SEND / DoPs to consider establishing more integrated nursing and pharmacy leadership arrangements within NHS Boards to take forward the quality, efficiency and effectiveness work as recommended in both the NHS Scotland Stoma Care Quality and Cost Effectiveness Review (2016) and in the NSQIG Report (2019).

Section 1

Introduction and Background

1.1.1 Stoma care affects a large number of patients across NHS Scotland. It is an area where there is evidence of increasing expenditure, with over ordering and wide variation in product usage and level of patient monitoring reported across the United Kingdom (U.K) (1,2).

1.1.2 It is widely recognised that where there is variation in healthcare, this can impact on quality of care and patient outcomes. Unwarranted variation does not add any clinical value and contributes to waste (3-5). Such variation can be linked to demographics, deprivation and patient preference; however, ‘unwarranted variation’ refers to the over-use or under use of different aspects of healthcare, products and services.

1.1.3 Recognising and reducing unwarranted variation and waste is therefore an overarching theme from key healthcare policy documents including the recent NHS Scotland Quality Strategy and Realistic Medicine Reports (6).

1.1.4 The NHS Scotland Stoma Care Quality and Cost Effectiveness Review (2016) identified that all areas of ostomy product use were in excess of established guidelines; identifying waste and unwarranted variation. Overall, 26 recommendations were identified that relate to effective and efficient stoma care and product prescribing practice (7).

1.1.5 This provided the rationale to seek clinical leadership from the Scottish Executive Nurse Directors Group for development of the National Stoma Quality Improvement Group (NSQIG) to identify and drive a once for Scotland approach that would address effective and efficient stoma product prescribing practice, aligned to the strategic narrative of key healthcare policy documents.

1.1.6 Recommendations from the National Stoma Care Cost and Quality Review (2016) that align to the work of NSQIG include:

- NHS Boards should maximise effective prescribing through a system of review, to ensure that expenditure is appropriate and thus ensure resources available to patient care can be maximised.
- NHS Board should develop a system of ‘Trigger Tools’ in line with protocols in NHS England to ensure there is no oversupply and to minimise waste.
- NSS NP and NHS Boards should bring the provision of non-bag products or accessories into line with standard protocols established in the NHS in England.

1.1.7 The National Stoma Quality Improvement Group Short Life Working Group (NSQIG) was subsequently commissioned by the Scottish Executive Nurse Director (SEND) Group and established in February 2018 under the leadership of the Scottish Deputy Nurse Director Forum (SDNDF). The group was commissioned to take forward the recommendations from the National Stoma Care Cost and Quality Review (2016) and consider the wider opportunities for improving the quality, effectiveness and efficiency of stoma care.

1.1.8 The Terms of Reference for the NSQIG were agreed with the wider stakeholder groups and approved by SDNDF (Appendix 1). Membership for NSQIG included: Health Board Stoma Nurse representation (regional), community pharmacy representation, Public Health Pharmacy representation, Health Board Lead, Pharmacy representation, Health Board Prescribing Team representation, General Practitioner, Colorectal Surgeon, Procurement and prescribing analyst support.

1.1.9 The aim of NSQIG was to identify, prioritise and progress areas of work requiring a national approach which will complement current stoma quality & efficiency activities across NHS Scotland Health Boards.
**NSQIG Key Objectives:**

1. Review the current product prescribing data across Health Boards and identify and develop opportunities for optimal data reporting to drive quality and efficiency.
2. Review current Health Board formularies and scope the feasibility of a National evidenced-based ostomy product formulary that could be used as an equitable and pragmatic aid to decision making.
3. Review current processes for product access identifying alternative models to GP prescribing to support timely, efficient, equitable patient product access.
4. Identify the process for measuring effectiveness of product use and patient outcomes with minimal annual patient-reported outcomes measures (PROMs) that includes patient-related feedback.
5. To review the role of e-health / assistive technology in stoma care and identify opportunities for quality improvement in patient care.
6. To explore effective partnership working with Dispensing Appliance Contractors that would support data sharing of product use and develop variance monitoring against agreed national guidance.
7. To identify clinical, financial benefits and risks from implementation of processes identified from this SLWG activity and include this in project report and action plan.

**1.2 Strategic Context**

1.2.1 The National Clinical Strategy sets out a high level vision to guide future healthcare service provision across primary and secondary care. Primary healthcare is planned around integrative working to support shifting the balance of care from secondary care to primary care. To support the delivery of the Clinical Strategy and the Transforming Primary Care Programme will aim to deliver integrative working by medical, nursing, pharmacy and allied healthcare professionals. This underpins the delivery of the new GP contract which will see more complex care provided by GPs. In addition, the Chief Medical Officer’s report on Realistic Medicine gives a clear direction of value-based healthcare as an approach to maximise resources and evidence effective care through improved patient outcomes [34, 35].

1.2.2 Value-based healthcare is an approach incorporated into UK health policy documents: The Right Care NHS England, Prudent Healthcare NHS Wales and Realistic Medicine NHS Scotland. The overall aim of value-based healthcare is to optimise patient care by delivering the best possible outcomes for patients in the most efficient way and ensure that resources are allocated for maximum value [36]. Value-based healthcare needs to be supported by robust data providing professionals and services with evidence that care is improving patient outcomes. For stoma care, this translates to evidencing effective, equitable person-centred care for ostomy patients across NHS Scotland and reducing unwarranted variation and waste [35, 36].

1.2.3 This strategic narrative is evident throughout the wider healthcare legislative and strategic policy drivers; The Health and Care (Staffing) legislation, Transforming Roles Programme (Chief Nursing Officer Directorate) and Achieving Excellence in Pharmaceutical Care aim to develop workforce capacity and capability to support transformation across primary and secondary care [3, 7].

1.2.4 These key strategic drivers help to inform how stoma care provision can be delivered with an outcome focused, integrative approach across primary and secondary care. A value-based approach should underpin stoma service delivery, maximising resources, reducing unwarranted variation and waste and evidencing improved patient outcomes. This approach will also address key National Health & Social Care Outcomes [3].

1.2.5 National Health and Social Care Outcomes that align to NSQIG include:

- Outcome 3: People who use health and social care services have positive experiences of those services, and have their dignity respected.
- Outcome 4: Health and Social Care services are centred on helping to maintain or improve the quality of life of people who use those services.
- Outcome 8: People who work in health and social care services feel engaged with the work they do and are supported to continuously improve the information, support, care and treatment they provide.
- Outcome 9: Resources are used effectively and efficiently in the provision of health and social care services.

1.2.6 NHS Scotland Healthcare policy documents that inform this work are:

- Stoma Care Quality and Cost Effectiveness Review Scottish Government (2016)
- National Clinical Strategy (2016)
- Chief Medical Officers report on Realistic Medicine (2016, 2018)
- Achieving Excellence in Pharmaceutical Care (2017)
- Primary care transformation (2017)
- General Medical Services Contract in Scotland (2018)
- Transforming Nursing Roles (2018), Excellence in Care (EiC) (2017)

**1.3 Stoma Care and Quality**

1.3.1 A stoma is a surgically formed opening from either the digestive or the urinary tract system to provide an exit point for body waste which is collected via a stoma appliance (pouch). Stoma surgery may be a temporary or permanent option to treat a variety of conditions such as cancer and inflammatory bowel disease [1].

1.3.2 For some patients a stoma may represent an improvement in health status from a distressing bowel dysfunction, but for others a stoma may compromise their quality of life. Ensuring that patients are prescribed clinically effective and appropriate stoma appliance products can greatly improve their quality of life and support independence [15, 17].

1.3.3 Following surgery, Stoma Nurse specialists initiate the process of selecting the most appropriate appliance product for that particular patient, taking into account their body shape, lifestyle and stoma size to provide protection and security from leakage and skin damage. A wide range of appliance products is available in primary care that the majority of patient’s access through a prescription issued by their GP with the subsequent supply from a dispensing appliance contractor (DAC), a community pharmacy (CP) contractor or from a dispensing doctor.

1.3.4 Effective appliance selection, prescribing and patient monitoring in primary care can ensure appropriate use of stoma products, provide early detection and earlier intervention to manage stoma complications, and deliver up to 20% reduction in stoma expenditure by improving patient outcomes and reducing waste [1].
1.3.5 Stoma-related complications impede recovery, impact on appliance and accessory product use and negatively affect quality of life. However, the reported incidence varies across the literature (17,18,19). A systematic review of randomised controlled trials reporting incidence of stoma-related complications was performed to provide a comprehensive summary of existing data (17). This review reported variation in methods across studies and that definitions of complications were inconsistent and poorly defined.

1.3.6 Stoma complications such as leakage, peristomal skin complications, hernia, infection, stoma retraction, ischemia and prolapse can occur as an early complication, within 1 month of surgery or as a late complication after the first post-operative month (17). The difficulties associated with stoma morbidity may be influenced by many factors such as age, gender, obesity, stoma type and body profile, stoma site, reason for surgery and co-morbidity with frailty and cognitive impairment in the ageing population (17,18,20). The reported incidence of stoma complications ranges from 2.9% to 81% with the burden of such morbidity negatively impacting on quality of life for patients in addition to significant financial impact to healthcare (17). Appliance leakage, which is correlated to peristomal skin complications, are the most commonly reported stoma-related complications across the literature and associated with increased appliance and accessory usage (17,18).

1.3.7 Improving quality of care is a long term and ongoing priority across all aspects of healthcare with an emerging theme of value-based care and demonstrating improved patient outcomes across key themes of safety, effectiveness and patient experience (1). The key to quality stoma care is the provision of safe, effective value-based care or interventions that can be demonstrated by data-driven improved patient outcomes (19).

Measuring the incidence of adverse events and outcomes of interventions and sharing this information will support healthcare professionals providing stoma care to identify areas for improvement, provide data on optimum product use, and support future research (19).

1.3.8 In the absence of a globally recognised stoma patient reported outcome measure (PROM), consistency in the approach to identify and report stoma-related complications and outcome measures needs to be considered and developed by Stoma Nurses which include benchmarking across services to identify and investigate clinical variation and product efficacy and variation (19).

1.4 Stoma Product Supply in NHS Scotland

1.4.1 A Scottish Government HDL 2005 (20) detailed new arrangements for stoma product supply across NHS Scotland which was introduced in 2007. The new arrangements included cessation of industry-sponsored Stoma Nurses and development of a procurement framework for product supply in NHS Scotland acute hospitals and community (17).

1.4.2 Dispensing appliance contractors and community pharmacy contractors have standards of care that form part of their contractual responsibilities to dispense stoma products. This includes knowledge of the recommended monthly appliance use and effectively utilising a process of escalating clinical review for patients who are over-ordering or report complications (10,11).

1.4.3 Across the UK, the inappropriate prescribing of stoma products and over-ordering in primary care is identified as having potential to contribute to a significant and negative clinical and financial impacts (1,3). Absence of an accurate stoma product specification (2,3) and poor communication of the appropriate product to patients (4,5) may be influenced by many factors such as age, gender, obesity, stoma type and body profile, stoma site, reason for surgery and co-morbidity with frailty and cognitive impairment in the ageing population (17,18,20).

1.4.4 Legislation governing the marketing of licensed medicines, particularly with regard to direct marketing to patients, does not apply to stoma products. Therefore, the commercial marketing of stoma products through online industry-supported websites can influence patients to request the readily available samples of these products, which in time, often as a result of a follow-up contact call, are then added to next prescriptions and subsequently to the repeat cycle.

1.4.5 Secondary Care Product Supply NHS Scotland

National Procurement division at NHS National Services Scotland (NSS) lead on the provision of a Scottish national contract framework for a wide range of stoma appliance products. The national contract covers new stoma patients in acute hospital settings. Stoma Nurse Specialists from across NHS Scotland are nominated by NHS Health boards to work with NHS National Procurement providing clinical expertise within a clinical advisory panel to guide product choice for the stoma contract. Product pricing under an acute national contract differs from those applied in primary care which come under the auspices of the Scottish Drug Tariff.

1.4.6 Current arrangements are based on a discounted pricing structure which can influence selection of a product for use in secondary care. Any loss incurred by manufacturers at this juncture is likely to be recouped in the community sector through the significantly greater usage rate at a much higher price.

1.4.7 Primary Care Product Supply NHS Scotland

In primary care, stoma appliances and accessory products are provided to patients by a prescription mainly from their General Practitioner (GP), which can then be dispensed by either:

- A Dispensing Appliance Contractor (DAC)
- A Community Pharmacy Contractor (CP)
- A Dispensing Doctor (DD)

1.4.8 Primary care products are prescribed via an approved stoma product list hosted by NSS Information Services Division (ISD). The range of stoma products is wider in community as stoma manufacturers request new products to be added to the Scottish stoma prescribing list. https://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Stoma-Supplies/

1.4.9 National Procurement lead on the development and updating of The Specification of Requirements for Dispensing and Supply of Stoma Appliances to Patients in the Community for NHS Scotland (10), a national framework of stoma appliance services in the community.

The framework details service standards that all dispensing contractors must meet in order to be authorised to dispense and supply stoma appliances in the community. This includes standards set by Quality Improvement Scotland (2005) for the contractor’s product knowledge, knowledge of stoma complications and processes to escalate patients for clinical review. The framework also sets out and monitors the global fee for appliance contractors for dispensing, delivery and customisation, currently £3.8 million per annum.

1.4.10 Commercial marketing of stoma product samples through online industry supported websites can influence patients to request these products to be added to prescriptions. General Practitioners (GP’s) are not always in a position to apply the degree of scrutiny of stoma prescribing required to manage variance (1,5).

1.4.11 The Stoma Care Cost and Quality Review (2016) conducted an audit of community stoma appliance service involving stoma manufacturers, community pharmacies, appliance contractors, NHS Board Staff and a cohort of stoma patients (10). Overall, 26 recommendations were identified covering a range of areas associated with stoma care provision and cost effectiveness. Key recommendations from the national review have informed the direction of the National Stoma Quality Improvement short life working group.
1.5 Case for Change

1.5.1 Across the UK, over £260 million is spent annually on stoma products despite wide availability of stoma prescribing guidance. Stoma appliances and accessory costs in primary care can range from £780-£2,300 per patient per annum. In situations where there is inappropriate product use, the cost can rise above £6000 per annum [1,2,20].

1.5.2 Primary care stoma expenditure in NHS Scotland has risen by 65% over five years with a current expenditure of £31 million per annum. Applying robust scrutiny and more effective monitoring of prescribing could yield a financial benefit of £3 million from a 10% reduction and £6 million with a 20% reduction, delivering value-based care by reducing waste and improving patient outcomes [1,3].

1.5.3 Key findings from the stoma quality and cost effectiveness national review (2016) identified the following:

- Evidence of increasing community stoma expenditure with growth attributed to higher volumes of prescribed appliances and growth in accessory use.
- The range of products in primary care is wider and attracts higher costs than products in hospital as a result of pricing being aligned to the Scottish Drug Tariff.
- Primary care appliance benchmarked against appliance volume guidance produced in NHS England identified appliance over prescribing rates of up to 40% across all stoma types (colostomy, ileostomy and urostomy).
- Nearly all prescriptions in the community setting are issued by a medical prescriber (GP’s) with only 1% attributed to a non-medical prescribing practitioner.

1.5.4 In response to the 2016 national review, a selection of NHS Scotland Health Boards conducted reviews of stoma patients, sharing the following results:

- Evidence of over ordering and inappropriate product use.
- Evidence of products sent by DACs but not requested.
- Evidence of commercial influence with patients requesting “free samples” of products that are not part of their usual prescription.
- Patients using ineffective “older appliance products” that were not identified as “high spend but ineffective”, resulting in leakage and skin problems and not detected at the point of re-ordering the prescription.
- Average patient appliance expenditure was over £5000 per annum which reduced by 50% following review and appropriate product selection.
- NHS Fife reported savings of £60,000 following completion of reviews of 50 stoma patients identified as high expenditure outliers.
- Poor compliance to local Health Board Stoma Formularies.
- GP’s providing stoma prescriptions were unfamiliar with the needs of stoma patients and were not best placed to apply scrutiny to stoma prescriptions.

1.5.5 NHS Boards reported interest for national coordination of efforts to support effective and efficient stoma product prescribing practice. This set the scene to secure clinical leadership to identify and drive a “Once for Scotland” approach that would address effective and efficient stoma product prescribing practice, aligned to the strategic narrative of key healthcare policy documents [4-9].

1.5.6 A paper was submitted to the Scottish Executive Nurse Director Group (SEND) in 2017 highlighting trends of increasing community ostomy expenditure with appliance, accessory and prescription costs of circa £31 million per annum in 2016/17. This identifies a 65% increase in expenditure over 5 years with a 13% rise per annum: detailed in Figure 1.

2016/17 Community Expenditure consists of

- Stoma Appliances: £ 22.8 million
- Stoma Accessories: £ 4.2 million (18% of overall stoma expenditure)
- Appliance Contractor dispensing, customisation & delivery fees: £3.8m
- Total expenditure £31 million

1.5.7 A similar analysis of the number of ostomates across NHS Scotland in Figure 2 show a 10% increase over 5 years with a 2% rise per annum

- It is estimated that approximately 2000 new stomas are performed annually.
- Approximately, 50% of stomas will be permanent
- >10,000 patients have permanent stomas in NHS Scotland.
1.5.8 Additional evidence, highlighted in Figure 3, identify that stoma care lacks an established national focus which is in place for other clinical areas across NHS Scotland with high product expenditure.

Figure 3 details clinical areas that have established national groups with analytical support that focus on delivering value-based effective and efficient care:

- Orthopaedics: (National group to improve outcomes from Hip & Knee surgery)
- Agency Nursing: (National group to improve safe, cost effective agency staffing)
- ONS: (National group to improve optimal use of oral nutritional supplements and cost-effective prescribing)
- Stoma care: rising expenditure and no established national group to support delivery of value-based effective and efficient care.

1.5.9 Increasing community stoma product use is due to a number of factors:

- Colorectal cancer survival rates are increasing in Scotland, which reflects improved screening and earlier intervention, hence the prevalence of stoma patients is increasing year on year, particularly long term patients (ISD 2018).
- Increasing elderly population with more people living longer with a permanent stoma
- Commercial marketing and promoting of products through samples via industry patient websites, patient support group ‘open days’ where industry representatives present a range of products and samples
- Evidence from NHS Board audits of over prescribing, inappropriate product prescribing and patient stockpiling products they do not use
- Lack of scrutiny around how these key product areas are monitored
- GP prescribing, with overburdened workloads and only general knowledge of stoma care and product use.
- Research studies that evidence up to 76% incidence of stoma-related adverse events; leakage and skin complications that relate to increased appliance and accessory product use (16,17,19).

1.5.10 The case for change is compelling and the Scottish Executive Nurse Director Group (SEND) agreed to commission a national group to focus on coordinating current NHS board stoma efficiency work - which would support existing recommendations from National Stoma Care Quality and Cost Effectiveness Review (2016) and align with key NHS Scotland Health care policy reports to deliver a “Once for Scotland” approach to prescribing and reduce unwarranted variance in care (3,4).

1.5.11 The National Stoma Quality Improvement Group Short Life Working Group (NSQIG) was established in February 2018 under the leadership of the Scottish Deputy Nurse Director Forum (SDNDF).

To further support the work of NSQIG three main sub groups were identified to deliver on key project objectives:

- Data Subgroup
- Formulary Subgroup
- Process Subgroup

In addition to the Subgroups above, wider engagement with patient representatives, the Commercial Sector; Community Pharmacy Scotland (CPS) and British Healthcare Trade Association (BHTA), was considered to be a priority. Separate Subgroup meetings were arranged with these respective stakeholder groups.

1.6 Stakeholder Engagement

1.6.1 The need to engage with patient groups was discussed early in the process of establishing NSQIG. It was identified that engagement should be via territorial NHS Board stoma fora.

1.6.2 The purpose of the NHS Board stoma fora was to provide a local platform to facilitate discussion of local stoma services with core membership representing local and national patient groups, Stoma Nurse, community pharmacy, and dispensing appliance contractors with input from Board personnel, advising on prescribing, finance and pharmacy. The development of NHS Board Stoma Fora was identified and recommended as part of the Scottish Government Supply of Stoma Products and review of stoma services as identified in the HDL 2005, (2).

1.6.3 The Stoma Care Quality and Cost Effectiveness Review (2016) identified local Health Board Stoma Fora as a useful platform to discuss comments and concerns with stoma care services. This national review also included within the 27 recommendations that “NHS Boards should review and update local stoma fora arrangements to ensure they are relevant, add value and are fit for purpose. At a national level the Scottish Government should continue to work with the Scottish Stoma Forum (SSF) as a reference group on policy and service provision R10” (3).

1.6.4 The SSF membership has wide representation including; Community Pharmacy Scotland and stoma trade industry body representatives, Scottish Stoma Nurse Group, appliance contractors, NSS NP and an NHS Board colorectal surgeon who acts as chair of the SSF. There are also 3 patient support organisation members representing; ileostomy, colostomy and urostomy patients.

1.6.5 NSQIG established engagement with the SSF, circulating NSQIG Terms of Reference, Stoma Fora Briefing paper and noting that there were NSQIG members who were also members of SSF. NSQIG agreed that additional patient engagement should be directed via the NHS Board Stoma Fora. The chair of NSQIG attended SSF to provide a detailed update on the progress of the groups’ work in October 2019.

1.6.6 In order to identify current status of NHS Board Stoma Fora development, a scoping exercise was conducted by NSQIG. NSQIG developed a questionnaire to circulate via Scottish Stoma Nurse Group to their local stoma fora.

1.6.7 10 NHS Boards out of 14 were included in the scoping survey. Exclusions were smaller NHS Boards; Western Isles, Orkney and Shetland, who do not all have a Stoma Nurse and frequently are included with neighbouring larger NHS Boards to discuss any issues with stoma services. (Full analysis of this survey is included in appendix 2)

1.6.8 Key Findings from this high level scoping survey were:

- 100% response rate from 10 NHS Boards surveyed.
- 60% (n=6) of NHS Boards surveyed had established stoma fora.
- Leadership of NHS Board stoma fora is mainly from pharmacy.
- There was variation across NHS Board stoma fora around frequency of meetings which range from 6 months – 2 years with meetings convened if issues arise.
• Across the established NHS Board stoma fora, membership is varied and includes representatives from pharmacy, stoma nursing, finance, procurement, dispensing contractors and patient representation.

• 70% of NHS Board stoma fora have a directory or written information available for patients detailing local or national groups.

Recommendations from NSQIG following this survey were:

• That NHS Boards who do not yet have established stoma fora should be encouraged to do so to meet the recommendations from the Stoma Care Quality Review (2016). In addition, Boards should explore the use of technology for remote areas as a means of including healthcare professionals and stoma patients in a dialogue to review and improve on stoma care.

• An effective governance process should be adopted for all established stoma fora to include terms of reference and recording of minutes for meetings.

1.6.9 To support engagement, NSQIG circulated a briefing paper which explained the purpose and key objectives and also an offer to meet with local Stoma Fora to inform the work related to NSQIG. Only three Board Stoma Fora responded to this invitation. This briefing paper was also circulated to Prescribing Leads via Scottish Pharmacy Practice and Prescribing Advisors Association (SP3AA).

1.6.10 NSQIG also identified the need for wider stakeholder engagement and formed subgroups with British Health Trade Association (BHTA) and Community Pharmacy Scotland (CFS).

Section 2

The data sub group

2.1.1 This subgroup was formed to give detailed consideration to the availability and quality of data available to NHS Boards and to make recommendations in relation to this. The key outcomes of the subgroup include:

1. Development of a reporting template with agreed metrics that support stoma product trend / variance / patient level data to support a consistent process for stoma data analysis across NHS Scotland.

2. Identification of patients for whom patient-level data is available who, on the basis of this data, appear to over or under use of stoma products benchmarked against national guidance which will assist in the early detection of patients with potential problems that may require clinical review.

3. Scoping of current data intelligence and utilisation across Health Boards; prescribing teams, Stoma Nurse Service, commercial dispensing appliance contractors and community pharmacy, to identify variation and areas of good practice which would inform development of a standardised approach to data collection.

4. Development of a suite of prescribing intelligence indicators and clinical indicators to support monitoring variance and key patient adverse event monitoring.

5. A high level logic model to identify the key data sub group activities, issues and short, medium and long term outcomes (detailed in Appendix 3)

2.1.2 An early action for the subgroup was to scope key areas within stoma care that are sources of stoma data intelligence. These key source areas are identified in figure 4.

The data subgroup devised questionnaires to scope current data intelligence across the following identified areas of potential stoma data sources.

2.1.3 NHS Scotland Prescribing Leads Survey

NHS Board Prescribing Leads and their teams are responsible for monitoring both medicine and appliance expenditure. A questionnaire was developed to assess stoma data intelligence and utilisation used by Health Board prescribing teams. The questionnaire was circulated to Health Board prescribing leads (n=14) via Scottish Practice Pharmacy and Prescribing Advisors Association (SP3AA). The response rate was 93% (13/14 Health Boards)
Key Findings:

- 63% report that stoma is listed on their Health Board prescribing action plan.
- 43% report they collate stoma patient numbers with only 2 submitting numbers.
- 70% report that they review stoma patient product selection with variance in how often this is performed.
- 23% report they do not issue guidance on recommended rates of product use to help identify outliers (excessive use).
- 69% report they do not use a standard set of metrics to search for stoma product use.
- 53% do not use PIS data to identify patients where prescribing indicates under/over use that may require referral for clinical review.
- 54% report that stoma is listed on their Health Board prescribing action plan.

Note: The findings of this high level review suggests that a level of variation exists across NHS Boards with limited clarity of actual stoma patient numbers. Variation also exists in the process of identifying over / under use of stoma products which would identify the potential need for a clinical review.

2.1.4 NHS Scotland Stoma Nurse Survey

A data survey was circulated to NHS Scotland Health Board Stoma Nurses via the chair of Scottish Stoma Nurse Group (SSNG). This included a draft set of clinical indicators for Stoma Nurses to review and give comment.

- In total 12 Stoma Nurses from across 10 NHS Boards provided comments giving a response rate of 83% (10/12 Health Boards who have Stoma Nurse).

- It was noted that 2 small NHS Boards do not have a Stoma Nurse due to low patient numbers. Direct patient support is provided by local healthcare teams who access specialist nurse advice in a regional approach.

- Stoma Nurses are recognised as clinical experts in stoma care providing guidance of stoma appliance and accessory product use and for the clinical management of stoma complications (1, 3, 20).

- As reported in the prescribing team survey, any identified over-use of prescribed products or any identified stoma problems by other professional groups are usually referred to Stoma Nurses. The data subgroup identified that Stoma Nurses are a potential source of rich clinical data capture, in particular appliance review clinical data.

2.1.5 Key findings from Stoma Nurse Survey:

- n=2 of health Boards responding report that they perform annual audit of stoma service.
- NHS Board Stoma Nurses report documentation of the following common stoma-related adverse events: Leakage (100%), Peristomal skin problems (100%), Odour (64%), Difficulty removing / applying appliance (73%), Parastomal Hernia (100%)
- 100% of Stoma Nurses document the outcome of treatment/advice for stoma adverse events
- 58% of Stoma Nurses reported using a database which consist of a combination of industry-sponsored databases and local bespoke NHS board data bases.
- Most NHS Board stoma nurses receive reports of under/overuse from a variety of sources that include DACs, Community Pharmacy, Community prescribing teams and GP’s, though this varies in consistency and quality.

2.1.6 Stoma Nurse Quality Performance Indicators (QPI)

The only published quality indicator is within the colorectal cancer QPI which relates to the percentage of people who have seen a Stoma Nurse for stoma siting. In the absence of published stoma clinical / quality indicators that relate to improvements in stoma related complications, the data subgroup developed a draft suite of QPIs as part of the Stoma Nurse survey.

QPI development and analysis may be a useful mechanism to evidence quality improvement in stoma care delivery with analysis to capture clinical and financial value based care. NHS Scotland Stoma Nurses reviewed a draft suite of QPIs and agreed that this was an area for further refinement.

The main findings:

- Despite some clinical data capture of adverse events, the current Stoma Nurse data capture, relying on industry databases and bespoke databases does not support consistent capture of stoma adverse event data as there is no coding or linkage to data held within NHS Scotland which affects data extractability.
- The lack of extractability of clinical data means that stoma patient adverse events and clinical outcomes cannot be captured or benchmarked across NHS Boards.
- It is also important to note that the literature reporting incidence of stoma complications such as leakage also relate these complications to patient factors such as obesity and co-morbidities (16,17,18).
- The collection and reporting of accurate clinical data from across NHS Boards would enable correlation and comparison and provide a focus to drive improvement.
- Significantly, the stoma industry has more access to detailed stoma clinical data than many NHS Boards.

Recommendation 2

SEND to consider development of a national approach to support the development of a national stoma care minimum dataset, aligned to the established Excellence in Care (EiC) assurance measures, enabled by digital solutions, to improve monitoring of patient outcomes. This will aim to reduce current reliance on use of industry data software by NHS Board employed healthcare professionals.
2.1.8 Commercial data

The data sub group identified that commercial data would include commercial organisations that are involved in dispensing and supply of stoma products as identified in the Stoma Service Specification Document from National Procurement. These include:

1. Dispensing Appliance Contractors (DACs)
2. Community Pharmacy Contractors (CP)
3. Industry suppliers who have developed Stoma Nurse databases and web based sites that provide information to patients on stoma problems, self-care management and product information.

2.1.9 When a patient has had stoma surgery formation, the hospital Stoma Nurse will discuss how the patient can access stoma products in the community. Access to stoma products is via a DAC, Community Pharmacy or Dispensing Doctor, with the choice determined by the stoma patient prior to hospital discharge (2.10).

2.1.10 SLWG data analysis identifies approximately 80% of stoma patients use DACs with 20% using Community Pharmacy. Stoma product prescriptions are sent via the patients GP to either DAC or Community Pharmacy who then arrange dispensing of the prescribed stoma products.

2.1.11 Dispensing appliance contractors and community pharmacy contractors have standards of care that form part of their contractual responsibilities to dispense stoma products. This includes knowledge of the recommended monthly appliance use and a process of escalating clinical review for patients who are over-ordering or report complications (10,11).

2.1.12 Key members of the data subgroup accepted an invitation to visit a DAC (Fittleworth Scotland) in Glasgow with approval of NSQIG Chair. The aim of the visit was to understand what data commercial organisations collect and how this data is used.

Key Findings from Fittleworth Visit:

- Fittleworth check patient product supply via telephone:
  - Screening questions are used (these were not shared at the visit)
- An annual customer service survey is conducted
- Fittleworth use Provis; a software system that can capture patient appliance and accessory use
- Provis is marketed as a free online data management tool that provides data and visibility of product use.
- If requested, Fittleworth Scotland can provide NHS Board Stoma Nurses with monthly product use reports.
- It was noted that whilst these reports may be helpful to Stoma Nurses, reliability and validity of the data is not known.
- It is also noted that visits to other DACs who operate across Scotland could not be performed within the project timescales, however the industry data survey in (2.1.13) enabled further exploration of data collated and provided by DACs.

2.1.13 The Industry Trade Body: British Healthcare Trade Association (BHTA) represents Dispensing Appliance contractors, many of whom are linked to stoma product manufacturers. BHTA members of the subgroup were involved with the development of an industry data survey acknowledging the need to understand what stoma patient and product use data is currently being collected by the industry within current interfaces.

2.1.14 Key Results from Dispensing Appliance Contractor survey

- N=7 DACs responded from a total number of 8 who operate in NHS Scotland
- All DACs collect data on stoma patients who use this service for dispensing of prescribed products.
- 80% identify patients that may be over/ under ordering products.
- 43% of DACs do not provide reports to NHS on product use and or adverse events.
- Those who do provide reports send these to:
  - Stoma Nurses (100%)
  - Prescribing leads (75%)
  - NHS Boards (25%)
- There is variation in the process of reporting of leakage and skin problems that may require additional products or change in products and variation in the process of escalation of patients for clinical review.

2.1.15 Key Findings

- There is variation in processes surrounding the patient data collected by DACs with 43% not providing reports to NHS Boards. It should be noted that where data is provided to NHS Boards, the reliability and validity of patient data is not under the control of NHS.
- The reports which do go to health care professionals vary and appear to be offered on request.
- The survey also highlighted significant variation on how problems are escalated for clinical review which would appear not to be consistent with the published standards of care for Patients Industry and Professional Forum (11) that also form current contractual responsibilities within the NHS Scotland community Framework (10).
- These standards detail the required knowledge of service staff in stoma care, product knowledge, monitoring of monthly usage identifying common problems and when to refer to Stoma Nurses which includes clinical problems and deviation from normal ordering pattern.

Note: It is crucial that there is reliable clinical data which reports the stoma complications or adverse events and that these can be identified by NHS Boards in order to focus on understanding why complications are occurring and provide a focus for quality improvement measures to improve patient care.
2.2 NHS Scotland Stoma Patient Data

2.2.1 Following initial discussion with NSQIG leads and ISD analysts, a series of data measures/data metrics were proposed to support a pragmatic approach to stoma data analysis and avoid generating extensive data reports. An example of the metrics at national level is detailed in 2.2.8. Figures 1a – 4a

2.2.2 It was acknowledged that the stoma patient population is dynamic due to the number of patients that have a temporary stoma which will be surgically reversed. A temporary stoma may be reversed in 3-9 months after surgery depending on the reason for formation, i.e. to allow the bowel to heal after injury or to enable chemotherapy and or radiotherapy to be given following cancer surgery.

2.2.3 The NHS Board scoping exercises showed that information to determine accurate numbers of stoma patients was challenging to access. In addition, ISD identification of temporary stoma patients is challenging due to coding issues.

2.2.4 For analysis purposes, NSQIG data identified each unique stoma patient as having an appliance (bag) dispensed in any quarter of the year.

2.2.5 Long term patients with a permanent stoma were identified as having had an appliance dispensed in each of four consecutive quarters. As a number of codes are used are used in colorectal surgery, it is acknowledged that this analysis of long term patients is a proxy measure and may not be wholly accurate, as appliances can also be used to collect fistula and wound exudate. The High Impact Actions for Stoma Care (20) estimate that 50% of stomas are permanent with no clarity to support this data. The figures for NHS Scotland detailed below from the analysis conducted as part of this review

NHS Scotland stoma patient numbers for 2017/18 include:

- Total number of stoma patients in NHS Scotland: 19,193
- Product expenditure: £27.1 million (excludes customisation, dispensing & delivery costs)
  - Appliance: £22.8 million
  - Accessory: £ 4.2 million (16% of all costs)
  - Global fees for customisation, dispensing & delivery: £3.8 million
- Total expenditure = £ 31 million
- Long term patients: 11,000 (57% of all patients dispensed)
- Long term patients account for 76% of appliance costs

2.3 Stoma Data Analysis Charts and Commentary

A number of key metrics have been proposed by the data subgroup and examples of these are shown at a national level below. These data are based on colostomy, ileostomy, urostomy and dual ostomate patient cohorts, identified at patient level in ISD Patient Information System (PIS).

It is important to note the metrics presented here are useful for looking at variation in cost and have been designed to look at differences in spending on these patients by Territorial NHS Boards. A standardised approach offers a different perspective to the information held on data platforms that are used for the day to day management of patients.

Note: There is a difference between clinical management information systems and Nationally held datasets used for the analysis presented here. Moreover, although the information shown below is useful to demonstrate the variation in costs by patient group, this is not indicative of either good or poor quality of care.

2.3.1 CHI Capture and Cost Per Treated Patient (CPTP) Metrics

The processing of community prescriptions, enables data collection on the item(s) supplied, the associated quantity and costs, the prescriber and associated organisations, the type of dispenser including appliance supplier, community pharmacy or dispensing doctor at the date of claiming.

For over 90% of prescriptions for stoma products processed in Scotland there is an associated patient Community Health Index (CHI) number. The presence of a valid CHI number allows a patient cohort analysis in relation to age, gender, location and deprivation.

Importantly, it enables the calculation on average Cost Per Treated Patient (CPTP), which is the costs of item(s) attributable to valid CHIs divided by the number of identified patients.

The CPTP metric considers the cost and usage variation in the designated cohort only, rather than using a population denominator wherein prevalence may vary.

Note: The costs below relate only to the price of the devices and do not include additional on-costs (customisation, delivery and dispensing fees).

2.3.2 Data Subgroup Metrics

The data reported is representative of the following areas of stoma prescribing:

- PTP by ostomate group.
- CPTP by age.
- CPTP by SIMD (Scottish Index of Multiple Deprivation).
- Ostomates, age and SIMD CPTP by dispenser type.
- Appliance usage above Association of Stoma Care Nurses (ASCN) recommended level by ostomate device type.
- Appliance usage below ASCN recommended level by ostomate device type.

Figure 1a. Cost per Treated patient by Ostomy Type (All Dispensers)
Financial Year 2017 (Source ISD Scotland)

Note: This figure shows the variation in cost per treated patient (CPTP) for ostomy bags by ostomate type for all dispensers. The size of each circle is proportional to the number of patients in the cohort.
Figure 1b. Cost per Treated Patient by Ostomy Type and by Dispenser (Financial Year 2017) (Source ISD Scotland)

Note: This figure shows the variation in cost per treated patient (CPTP) for ostomy bags by ostomate type and by type of dispenser:

- The size of each circle is proportional to the number of patients in the cohort.
- For all ostomate types, appliance suppliers (AS) dispense to the largest number of patients and have the highest cost per patient, when compared with patients who are dispensed from community pharmacy (CP).
- A small number of patients also receive appliances from dispensing doctors (DD).

Figure 2a. Cost per Treated Patient by Ostomy Type, by Age, All Dispensers (Financial Year 2017) (Source ISD Scotland)

Note: This figure shows the variation in cost per treated patient (CPTP) for patients receiving colostomy bags, by age group and for all dispensers.

- The size of each circle is proportional to the number of patients in the cohort.
- The greatest number of patients and highest cost per patient are in the cohorts aged 50 and over.

Figure 2b. Cost per Treated Patient by Ostomy Type, by Age, by Dispenser Type (Financial Year 2017) (Source ISD Scotland)

Note: This figure shows the variation in cost per treated patient (CPTP) for patients receiving colostomy bags by age and by type of dispenser:

- The size of each circle is proportional to the number of patients in the cohort.
- The greatest number of patients and highest cost per patient are in the cohorts aged 50 and over that may reflect higher incidence of cancer and inflammatory bowel disease.
- More patients are in the cohort dispensed by the appliance supplier (AS), for each age group and the CPTP per patient in the AS group when compared to those patients dispensed by community pharmacy (CP) and dispensing doctors (DD).

Key:
- AS: Dispensing Appliance Contractor
- CP: Community Pharmacy
- DD: Dispensing Doctor
Note: The cost per treated patient (CPTP) for ileostomy patients is highest in the most deprived SIMD (SIMD 1) but the number of patients in each quintile is similar.

Note: This chart shows the percentage of patients dispensed stoma bags, which are either over or under the prescribing guidelines (ASCN) limit for each ostomate type.

A number of patients are prescribed out with these guidelines for colostomy, ileostomy and urostomy.
2.3.3 Discussion and Summary

2.3.4 The data presented in the above figures show an example of analysis for the cost per treated patient for all patients.

2.3.5 A number of additional indicators are also available for long term ostomates and associated patient for all patients. As a significant proportion of costs are located in this longer term group, these data should be of interest to NHS Boards. Standard reports are also available at GP practice level for review if necessary. A separate set of analysis is also available to rank product costs.

2.3.6 A pilot evaluation of these metrics within NHS Board reports was performed in NHS Lanarkshire, NHS Tayside, NHS Lothian and NHS Ayrshire & Arran. Board prescribing leads found the report helpful, although some Stoma Nurses from the pilot boards reported initial issues with the utility of the data analysis in terms of how useful this was in their day to day clinical management of patients. It was agreed by all pilot boards, the sub group and NSQIG that the NHS Board report would be useful as a strategic level report, where a report discussion with prescribing leads/teams could support Board Stoma Nurses with data interpretation.

2.3.7 It is of significance that the CPTP varied significantly between CP and DAC’s. It is known that the CP share of the market has been in decline for some years with the possibility that some of this could be due to the marketing expertise of the DACs and manufacturers. Results from a small sample of participating pharmacies indicated awareness of a declining market with a reluctance to withdraw completely. The selection process applied in secondary care as to the choice of supplier on discharge was also cited as being a significant contributor to the decline in market share. Anecdotal comments on pharmacists not being sufficiently trained in this speciality and therefore unable to comply with the service requirements, e.g. customisation and provision of bags and wipes, although not founded, has possibly led to inaccurate perceptions of quality of the service provided by CP providers.

Recommendation 3

For resource requirements to be identified that would support the delivery of strategic level stoma product prescribing data reports to all territorial Boards, supporting the scrutiny and monitoring arrangements across prescribing and clinical teams.

Section 3

The Formulary Sub group

3.1.1 Key outcomes of formulary sub group

- Scope current NHS Scotland Health Board formularies identifying commonalities / variance
- Benchmark against evidence-based guidance.
- Develop a national formulary structure and key formulary categories to be used as a pragmatic, equitable decision aid for NHS Scotland.

3.1.2 It was the considered view of the subgroup, supported by NSQIG that development of a national stoma appliance formulary would not be considered at this juncture but the focus should be on appropriate appliance volume use. The group led to a position of access to a range of clinically approved accessory products.

3.1.3 There is limited evidence that supports the clinical efficacy of stoma accessory products such as skin protectors and if used they should for short term as a properly fitted ostomy appliance should provide comfort and confidence that the appliance will not cause odour, leakage and peri-stomal skin irritation (1). The ASCNNUK Guidance identify accessory products as routinely recommended, occasionally recommended and products identified as not recommended for prescription (10).

3.1.4 Currently there is over 4,500 appliance products and an extensive range of accessory products which are available for community prescription on the Scottish Stoma Supplies page published from ISD. As indicated in the national review (2016), new products have been introduced over time.

3.1.5 NHS Board reviews identified that some patients were using older appliance products that required additional accessory product use, indicating that these older products may be less efficient than newer products. This also highlights that early recognition of problems at the point of prescription could identify patients that may benefit from clinical review.

3.1.6 A selection of NHS board formularies (n=9) were reviewed for structure and content. All NHS Board formularies consist of appliance volume guidance and accessory product choice and volume guidance. There is variation in the format of formularies, accessory product choices and guidance on products not for prescription, such as deodorants and support underwear.

3.1.7 There is a need for consensus on the structure and format of stoma prescribing guidance to ensure equity of practice which would support reducing prescribing variance and support compliance monitoring.

3.1.8 Taking into account published guidance and collating best practice from NHS Scotland, NHS Board stoma guidance, a draft NHS Scotland Stoma Prescribing Guidance has been developed and is detailed in Appendix 4.

Recommendation 4

National prescribing guidance developed by NSQIG should be adopted across NHS Scotland to support NHS Board’s equity of practice and facilitate improved prescribing practice. Dispensing Contractors should be informed of the process, contained within prescribing guidance for reporting stoma related adverse events within a clinical escalation pathway.
Section 4

Industry / Professional Interface

4.1.1 NSQIG established engagement with key professional and commercial stakeholder groups which include; Scottish Executive Nurse Director and Deputy Nurse Director Group, Director of Pharmacy Group, Scottish Stoma Forum and Reference Group, Scottish Stoma Nurse Group (SSNG), British Healthcare Trade Association (BHTA), Community Pharmacy Scotland (CPS).

4.1.2 Separate NSQIG subgroup meetings were established with BHTA and CPS.

4.1.3 National procurement provided detailed information on commercial Value for Money (VfM) submissions from stoma manufacturers which have an impact on the industry / professional interface.

4.1.4 The stoma reimbursement (claw back) scheme was set up by National Procurement (NP) to obtain Value for Money (VfM) from stoma manufacturers. This VfM currently comes in two forms – reduced product costs and money paid back to NHSS as a rebate. All money received via the rebate is redistributed to NHS Scotland Health Boards (HB’s), and is proportionally split based on percentage of spend.

4.1.5 The value delivered to NHS Scotland does not equate to the full sponsorship value manufacturers provide in NHS England, although it does go some way to ensuring that NHS Scotland receive additional VfM from the manufacturers who supply products in Scotland.

Based on set criteria, reviewed and updated every two years, manufacturers are encouraged to provide additional value to Scotland by:

1. Reducing the cost of products supplied in NHS Scotland – i.e. the price paid in Scotland is lower than the drug tariff price, in place at the time in NHS England

2. Providing additional value for money products and services

Any VfM activities by stoma manufacturers must be demonstrated by submitted evidence, with appropriate information provided to audit trail any products or services delivered. The VfM offerings can be used to offset the rebate paid to NHSS, once evidenced to NP.

4.1.6 Over £300,000 was included in the VfM submissions from manufacturers for areas that include provision of software (data bases), education, travel to conferences, telehealth, samples and significant costs for training for NHS employed professionals including Stoma Nurses.

4.1.7 The chair of NSQIG discussed the impact of VfM and the industry / professional interface with the BHTA and the SSNG reinforcing the need for clearer governance and accountability regarding industry involvement with education events and meetings. An NHS Scotland National Conflict of Interest Policy is under development which will assist with this.

Section 5

The process sub group

5.1.1 The key outcomes of the process sub group were to:

- Identify the process for measuring effectiveness of product use and patient outcomes
- Identify alternative models to GP prescribing to support timely, efficient, equitable patient product access.

5.1.2 Early initial scoping by the NSQIG Steering Group was undertaken in a workshop led by the NSQIG co-chair which utilised improvement tools to map the current process for stoma product acquisition flow, capturing feedback of the positives and negatives across acute and community care.

5.1.3 The outcome of the data sub group, formulary sub group and wider discussion within the steering group and with commercial partners also identified areas for improvement which would support effective product use, prevention and early detection of stoma related adverse events in maximising and supporting self-care and supported self-care.

These include:

- A more integrated approach to support effective prescribing of stoma products.
- Provision of effective support and resource to maximise self-care and supportive care.
- Applying scrutiny of prescribing practice to reduce waste and unwarranted variation.
- Identifying alternative models to GP prescribing of stoma products.

5.1.4 The model of stoma care requires to be strengthened in the short term with increased scrutiny applied to the process of stoma prescribing to reduce unwarranted waste through inappropriate product use.

In the longer term alternative models to GP prescribing should be developed.

Recommendation 5

National Procurement (NP) to review and strengthen how it works with NHS Boards to provide improved governance, transparency and professional accountability in the commercial Value for Money (VfM) review process.

Recommendation 6

SEND to remit SDNDG to review the leadership, reporting and accountability arrangements with the Scottish Stoma Nurse Group in order to strengthen the professional governance and strategic work of this group.
5.2 An integrated approach to support effective prescribing and care review

5.2.1 The national stoma review (2016) identified community prescriptions are issued primarily by General Practitioners (GP’s) with only 1% attributed to nurse prescribers. It is acknowledged that the current reliance on GP’s for prescribing stoma products is not sustainable or effective. GP’s have limited knowledge of stoma product use, efficacy and volume. A product change requested by patients who may be influenced by commercial marketing is often challenged by GP’s as they are not overly familiar with stoma products.

In addition, GP’s are currently overburdened from an excessively high workload and are already stretched to provide services to an increasingly complex primary care population.

5.2.2 National approaches to Primary Care Transformation is supporting the development and integration of Advanced Nurse Practitioners, General Practice Nurse Prescribers, Advanced Clinical Pharmacists, Clinical Pharmacists and Pharmacy Technicians to contribute to the multidisciplinary team and support GPs to provide care to those with complex care needs.

5.2.3 Few of the Stoma Nurse workforce are independent prescribers and some of those who are pre

5.2.4 The Chief Nursing Officer Directorate (CNOD) Transforming Roles Programme has undertaken a national review of Clinical Nurse Specialist role and although still to report will focus on providing role definition, requirements for academic and clinical competency acquisition for nursing roles working at Level 6/7 of the NES Career Framework. For most, this will involve having independent prescribing skills which in the longer term may support a more integrative and multi-disciplinary approach to prescribing practice.

5.3 Applying scrutiny of prescribing practice to reduce waste and unwarranted variation

5.3.1 The data subgroup identified that 80% of stoma patients will access products via a Dispensing Appliance Contractor and 20% of stoma patients access products via a Community Pharmacy. There is evidence from the data analysis undertaken by NSQIG that cost per treated patient is lower in patients that utilise community pharmacy.

5.3.2 The data subgroup identified that 50% of stomas are permanent with this group considered as long term patients which account approximately 11,000 permanent stoma patients across NHS Scotland. Long term patients account for 76% of appliance costs. Patients with permanent stomas were identified in ISD as having a stoma prescription in all quarters; 1 year or over.

5.3.3 Whilst the choice of appliance contractor lies with the patient this is supported by the Stoma Nurse in the early stages of the care pathway following surgery. Community Pharmacy access can provide clinician support with additional medications, as evidenced in the formulary subgroup work, which identifies caution with certain medication use for stoma patients, in particular ileostomy patients.

5.3.4 Stoma Nurses provide regular review of new patients at defined periods for up to 1 year following surgery with some offering ongoing annual review. Access to nurse led clinics or telephone clinics is available to provide specialist review and advice to patients when identified by community pharmacist’s / appliance contractors as having problems.

5.3.5 The demography of stoma patients identifies an aging population who will be living longer with a permanent stoma and many will also have long term conditions which further supports the need for stoma patients to be able to easily access clinical review. It is also recognised by Stoma Nurses that home care services commissioned to provide support to stoma patients require education in stoma care to recognise stoma related problems and appropriately escalate for clinical review. This is currently variable in how it is delivered and is an area that Scottish Stoma Nurse Group could work with key health and social care partners to scope and deliver the educational requirements for formal carers.

5.3.6 In recognition of capacity issues with Stoma Nurses to routinely review all stoma patients, it is feasible for for stoma care to be supported by a primary care clinician (e.g. General Practice Nurse) for stoma care supported self-management, in line with other long term condition management activity, and be linked to a protocol that includes escalation to Stoma Nurses for specialist advice, review and intervention.

5.3.7 Pharmacy colleagues in NSQIG have suggested that serial prescribing could be considered as a legitimate option for stoma product prescribing where patients have stabilised and are managing. Serial prescribing is where the patient is dispensed medication for a 24 or 48-week period at regular intervals defined on the serial prescription. This allows medication to be dispensed for the 24 or 48 week reducing the workload of GPs. Increasing the use of serial prescribing is advocated in Achieving Excellence in Pharmaceutical Care 2017.

5.3.8 The use of Serial Prescribing could support implementation of appliance / accessory product prescribing guidance and once the prescription is approved following a Stoma Nurse giving advice, cannot be changed without further review. This approach could provide much needed scrutiny of prescribing practice and minimise product requests influenced by commercial marketing. The suitability of stoma patients for Serial Prescribing should be actively considered as part of the roll out of this approach across NHS Boards.

Recommendation 7
Primary Care Teams within NHS Boards to actively consider the use of serial prescribing, supported by Primary Care Pharmacists and Stoma Nurses, to improve the monitoring, effectiveness and efficiency of stoma prescribing.

5.4 Maximising resources to support self-care and provide effective supportive care.

5.4.1 Developing standard protocols for early detection and management of stoma related adverse events could support the wider primary care staff which include; district nurses, GPN’s, pharmacy and NHS 24 and home care services to provide a more consistent approach to stoma care in the community with a clear escalation pathway to Stoma Nurses to provide specialist intervention. The Scottish Stoma Care Nurse Group should lead this work, supported by senior nurse leadership, as they have the clinical expertise.

Recommendation 8
Scottish Stoma Care Nurse Group to develop stoma care quality assurance measures, aligned to Excellence in Care(EIC) methodology. Quality assurance should cover early detection and management of stoma related adverse events. An integrated approach should involve the wider primary care team and provide clear clinical escalation pathways to specialist advice and intervention.
5.4.2 Protocols could also support self-care using ‘Florence’ (Flo) telehealth monitoring which is part of Technology supported care (TEC) using standard ‘smart’ mobile phones to monitor and track patient care. Flo is widely used across a variety of health conditions such as diabetes, asthma, COPD, hypertension, inflammatory bowel dietary management and medication management (14,15). The benefits of Florence are that protocols can be uploaded to support self-care with tracking that can provide patient outcome data. NSQIG representatives from NHS Lanarkshire have reported that Florence telehealth monitoring is currently being used by Stoma Nurses to monitor stoma patients in the community.

Recommendation 9
That NHS Boards’ support Stoma Nurses to consider wider use of Technology Enabled Care such as Florence to support self-management, supported self-care, monitoring and outcome measurement.

5.5 Emerging Models of Care

5.5.1 The strategic narrative of the Health and Social Care Delivery Plan (6) and the implementation of the General Medical Services Contract (7) describes how clinical pathways, the role of the General Practitioner (GP) and other health and care professional roles and their workload will be redesigned to enable consultation and initiation of treatment which will include prescribing by the most appropriate primary care healthcare professional. The refocusing of the GP role will require some tasks currently performed by GP’s to be performed by a range of healthcare professionals within the wider primary care multi-disciplinary team, where it is safe, appropriate and improves care. Some of these tasks involve prescribing and management of agreed areas of primary healthcare provision (6,7).

The work of NSQIG has identified that the current model of GP stoma prescribing model is unsustainable, adding to an increasing prescribing burden to GP’s. Data intelligence from NSQIG scoping surveys and prescribing analysis have identified over prescribing of stoma appliances and accessories and identified a lack of prescribing scrutiny, which supports the need for redesign of the current stoma prescribing and care delivery model.

5.5.2 Exploration of alternative models to GP prescribing was a feature within NSQIG key objectives and in addition to the aforementioned opportunities for increasing capacity of independent prescribers across the primary care MDT, two emerging models of care were identified by the Process Sub-Group:

5.5.3 Model1: Independent Prescribing Model

This model describes an independent prescribing model, which supports the direction of advanced practice within primary care utilising nursing and pharmacy expertise. Within this model, stoma prescribing is redesigned to remove current GP prescribing to a community independent prescribing model. A similar approach has been developed in Rotherham, evidencing prescribing efficiency and improved patient outcomes (16).

5.5.4 Model 1 Overview

Independent stoma prescribing should be performed by primary care professionals who have completed an independent prescribing course and are sufficiently competent and knowledgeable in stoma care. This could incorporate community staff who currently provide stoma care; community nurses, clinical and community pharmacists and incorporate an integrated approach with secondary care based Stoma Nurses.

5.5.5 The perceived benefits include a consistent and person centred approach to care delivery aligned to the strategic narrative of the Health and Social Care Delivery Plan (6), reduction in GP workload, improved governance and prescribing scrutiny and support ongoing quality improvement.

5.5.6 Model 2: Non-Prescribing Model

This model would be an innovative approach to primary care stoma product access.

A non-prescribing model could utilise PECOS ordering system to order stoma products in place of a prescription.

5.5.7 Background

PECOS is a purchase to pay ordering system established across the public sector and in operation to order goods. Within acute and community services, PECOS is used to order goods from NSS National Distribution Centre. This system allows staff to order goods that have been uploaded into a catalogue. Catalogue products can be part of national procurement contracts or approved off contract products.

An innovative pilot project in NHS Glasgow and Clyde with Procurement and Child Health enabled parent’s access to PECOS to allow them to order products for their child via a bespoke product catalogue. Orders were sent to the child health hub within GG&C for clinical approval and transmitted to the supplier for home delivery (21). PECOS has also been used within diabetes care, where patients were supported to self-order through a similar bespoke catalogue, within an agreed budget supporting self-management. Triggers were set up to highlight patients who could potentially breach the agreed budget which would be flagged to the clinical team to review (21).

Benefits
- This approach was person centred, and supported efficient timely access to products.
- Promoted more control and self-management by families caring for children at home.
- Reduced labour intensive involvement of healthcare professionals from ordering products.
- Promotes increased visibility and value of product management information relating to child health and diabetes.

Discussion with GG&C procurement leads involved with PECOS Child Health provided information that stoma products were included in products used in child health and supports utilisation of this model to the wider stoma adult population.
5.5.8 Model 2 Overview

This model could be developed to support self-ordering or ordering via carers or a clinical hub, supported by a SPOC, assisting patients who are frail and or have cognitive problems. Adverse event management could be supported through approved pathways for direct or in-direct clinical review by local clinicians or via a single point of contact at NHS Board level. Using a contact at NHS 24 could also be considered as an option, utilising the established algorithmic clinical decision methodology already in place, adapted to incorporate stoma adverse event assessment with OOH management incorporated through OOH support and care. This approach could be used to check orders and for clinical triage/review, utilising technology enabled care such as Florence, NHS Near Me or Attend Anywhere. Current IT systems (clinical portal) could also be utilised to support e-communication and e-data collation of adverse events and patient outcome monitoring.

5.5.9 Both Models 1 and Model 2 are included in appendix 5 as high level descriptive models which would be developed further within a detailed business case. Model 1 supports the current healthcare direction of travel for independent nurse/pharmacy prescribers to be using prescribing and advanced clinical skills to manage identified patient caseloads that could improve access for patients and relieve pressure on GPs. Whilst there are wider programmes of work promoting the building of the independent prescribing capacity across primary care settings, it is acknowledged that this is not a short term solution and will take time for the capacity and capability to be fully embedded in practice.

Model 2 would not require prescribing ready resource and would if successful take the prescribing element entirely out of the process. Product ordering and usage monitoring could be greatly simplified and variance of usage at Board/individual patient level more easily detected and addressed. NSQIG agreed that it would be appropriate to subject both models to proof of concept testing before identifying a preferred option.

Recommendation 10
SEND/DoP’s to consider Proof of Concept evaluation of alternative models to stoma appliance and accessory product prescribing to see if improved patient outcomes and more effective and efficient product use can be achieved.

5.6 Workforce

5.6.1 A detailed workforce analysis was out with the scope of this short life working group; however, it is recognised that any future redesign/improvement work in stoma care will require workforce planning to support our future Stoma Nurse workforce.

5.6.2 It is acknowledged that stoma care is provided across primary and secondary care by a wider workforce than those in specialist roles i.e. stoma care support in primary care which includes; District Nurse, General Practice Nurse, General Practitioners and pharmacists. A product use and support role is also included in the specification for DAC’s with an expectation that patients will be linked back into the appropriate nursing service if circumstances require this.

5.6.3 Stoma Nurses provide specialist advice and intervention in secondary care with often dual roles as colorectal/Stoma Nurses. Not all Stoma Nurses provide community based follow up and care, although most provide outpatient follow-up and as a consequence the interface with primary care colleagues can be very variable.

5.6.4 It was evident from engagement with the Scottish Stoma Nurse Group that there were a range of other challenges facing this group of staff. There is significant variance in the AIC Bandings of staff operating with a Stoma Nurse specialist title/remit and this did not appear to relate closely to levels of practice as set out in the NHS Education Post Registration Career Development Framework. In the absence of a clear post graduate education framework, many Stoma Nurses appear to be dependent on industry sponsored educational programmes for preparation for role and ongoing CPD. In addition, the perception of many Stoma Nurses is that as a cohort of Clinical Nurse Specialists they are an ageing workforce and there is concern that there is not sufficient workforce planning activity across NHS Boards for the future professional requirements in succession planning to support this patient group.

5.6.5 It is recognised that wider healthcare workforce roles are changing, to support delivery of transformative work related to key healthcare policy drivers \(^9\). As a consequence, detailed workforce planning activities are being conducted across NHS Boards to plan delivery of the various transformation programmes. It is essential that Stoma Nurse roles are included in these workforce discussions at Board level.

5.6.6 Workforce planning for Stoma Nurses should be informed by the CNOD Transforming Roles Programme and the findings of this review. Workforce planning for Stoma Nurses should be informed by the CNOD Transforming Roles Programme and in particular the pending report into transforming Clinical Nurse Specialist roles. This should be used to inform the future educational and clinical preparation requirements for Stoma Nurses who work at different levels of the career framework. This work will require to be supported by NES in relation to forming the detail of the formal post graduate education requirements. In addition, support from NES should be asked to review with the Scottish Stoma Nurses the current education packages and opportunities, some of which are delivered in partnership with the industry.

Recommendation 11
NHS Boards to review future Stoma Nurse workforce requirements in line with CNOD Transforming Roles Programme and the findings of this review.

Recommendation 12
Scope how NES can work with Scottish Stoma Nurse Forum to develop a framework of post graduate educational and clinical preparation requirements for stoma care nurses in line with the NES Career Development Framework. This should include a review of the current industry supported education and CPD provision.
Section 6

Summary of Findings and Conclusion

6.1.1 Stoma care is an area of care that affects a large number of patients across Scotland (recent figures from NSQIG analysis place this at circa 19,193 patients). Ensuring that patients have access to the most appropriate care and effective appliance products can prevent and minimise stoma related complications of leakage and skin damage that negatively impact on quality of life.

6.1.2 Strengthening existing primary care stoma prescribing arrangements though effective appliance selection, monitoring and prescribing variance analysis will facilitate appropriate use of stoma products, provide early detection and management of stoma complications, and deliver up to 20% reduction in stoma expenditure by improving patient outcomes and reducing waste.

6.1.3 This would equate to approximately £6 million financial benefit which could be re-directed to support and deliver improvements in healthcare.

6.1.4 Alternative models to GP prescribing need to be progressed which support integrated MDT working across healthcare service boundaries and professional groups. This should also include proof of concept initiatives which evaluate non-prescription models of product provision.

6.1.5 This should be driven by a value based approach to deliver and the best possible outcomes for patients in the most efficient way, ensuring that resources are allocated for maximum patient, clinical and financial value.

6.1.6 This supports the strategic narrative from the Clinical Strategy, Realistic Medicine and is evident throughout primary care transformation policy.

6.1.7 The number of long term stoma patients is rising as is the age demography of this patient group leading to the same increases in numbers of multi morbidity and complexity as is seen across the rest of the population. This requires improved approaches to self-management and self-care and access to high quality care and support tailored towards the patients’ particular needs and choices. There is work to be done to be done in this respect and Stoma Nurses will continue to be key stakeholders in supporting this agenda.

6.1.8 Implementing the recommendations of this report will require a combination of nationally led actions and locally supported quality improvement actions. It is the view of NSQIG that in order to successfully co-ordinate this a national leadership group, similar to NSQIG is formed to continue with what would effectively be Phase 2 of this work.

6.1.9 It was recognised during the work of NSQIG that implementation of the recommendations from the NHS Scotland Stoma Care Quality and Cost Effectiveness Review (2016) was patchy across NHS Boards, with particular reference to patient feedback, quality monitoring and the establishment of Stoma Fora and identification of recognised Board Leads.

6.1.10 Furthermore in order to successfully implement the recommendations in Phase 2 of this work, engagement with a full range of stakeholders, including patient groups, independent contractors and industry will require to be strengthened at national and local level. This would be best supported by strong leadership alignment across nursing and pharmacy professions both nationally and locally.

Recommendation 13
SEND to consider continuing the work of NSQIG in the form of a national leadership group to progress the recommendations contained in this report as Phase 2 of this work.

Recommendation 14
SEND / DOPs to consider establishing more integrated nursing and pharmacy leadership arrangements within NHS Boards to take forward the quality, efficiency and effectiveness work as recommended in both the NHS Scotland Stoma Care Quality and Cost Effectiveness Review (2016) and in the NSQIG Report (2019).
References


National Stoma Quality Improvement SLWG Membership

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Appendices

National Stoma Quality Improvement SLWG Terms of Reference

NHS Scotland Stoma Fora Survey

NHS Scotland Stoma Fora Briefing Paper

NHS Scotland Stoma Prescribing Guidance