Interface
Clinical Services
an IQVIA business

STOMA PARTNERSHIP PROGRAMME

Remote service to identify and engage ostomates

Coloplast

V1.5 November 2020

SECTION 1: OVERVIEW OF THE SERVICE

1.1 INTRODUCTION & SERVICE SCOPE

The Stoma Partnership Programme is provided to practices expressing a desire to engage their ostomate population with the nurse led, tiered support programme. This service is fully funded by Coloplast as an aid to improving patient care with respect to the provision and management of ostomy appliance(s) and is delivered remotely by Interface Clinical Services Ltd. (Interface), an independent clinical services provider.

The service is designed to assist practices in implementing a systematic approach to the identification of ostomates across the practice population and to provide insight into the type, order frequency and cost of ostomy appliances and accessories. The service also includes sustainable community support to patients who register with Coloplast Charter, a unique telehealth and product delivery service.

Once an individual GP practice has agreed to implement the Stoma Partnership Programme, the following protocol must be strictly adhered to. The protocol details the procedure that the Interface service technology executive will follow within the scope of the service.

1.2 BACKGROUND

It is estimated that over 130,000 people in the UK (based on a prevalence figure of 0.24%) have a stoma and most will experience problems at some point.[1] It has been reported that up to 85% of ostomates have an issue with their current solution.[2] There are a number of common problems including skin irritation, blockage, leakage, difficulty attaching and removing, and sore skin and these can often be resolved with appropriate advice from a trained healthcare professional.[1] Despite this, many patients do not seek help when experiencing problems. For example, over two thirds of people experiencing sore skin will attempt to resolve the issue without support.[3] This may be in part due to a lack of awareness of issues relating to their stoma, and a fragmented service available to patients to seek support. This in turn leads to increased healthcare costs due to increased product use and product wastage and unnecessary referrals to specialist stoma services.

This service seeks to improve patient awareness by facilitating patient enrolment into a tiered, nurse led ostomate support service in order to provide an enhanced clinical pathway, which provides all CCG ostomates with access to specialist stoma care support.

1. **Burch J.** (2011) Management of stoma complications. *Nursing Times;* 107: 45, 17-20
2. **Coloplast.** (2015) Data from ostomy checks performed March – June 2015 (approx. 5,000 patients)
3. **Smith AJ et al.** (2002) Multidisciplinary care of skin problems in stoma. *Br J Nurs 2002;* 11(5): 324-30

1.3 AIMS AND OBJECTIVES

- To facilitate patient enrolment within the Coloplast Charter support programme, to allow all ostomates within the practice to access tiered clinical support appropriate to their level of need and to provide a clear pathway of accredited support including:
    - Clinically relevant support content
    - Clinically appropriate support
    - Regular stoma self-assessment
    - Regular assessments of wellness
    - Educating patients on appropriate usage of their stoma solution
    - Information on correct frequency of stoma usage to ensure that ostomy products are being ordered appropriately

- To assist in producing a register of all ostomates across the practice population, stratified to provide detail on type of appliance, order frequency and accurate spend data to identify patients or patient groups requiring support

- To provide a situational analysis report, benchmarking demographic breakdown, burden of illness insight, appropriate usage and cost analysis across the ostomate register to inform opportunities for service enhancement and efficiency savings in line with best practice and local guidelines

Whilst conducting the review service the Interface service technology executive will collate data, where authorised to do so, to provide the local NHS organisation with a report containing anonymous statistical data that will benchmark current management and cost/usage of ostomy products. This will assist the NHS organisation and individual practices to better understand service outcomes, care gaps, condition management planning and prioritisation.

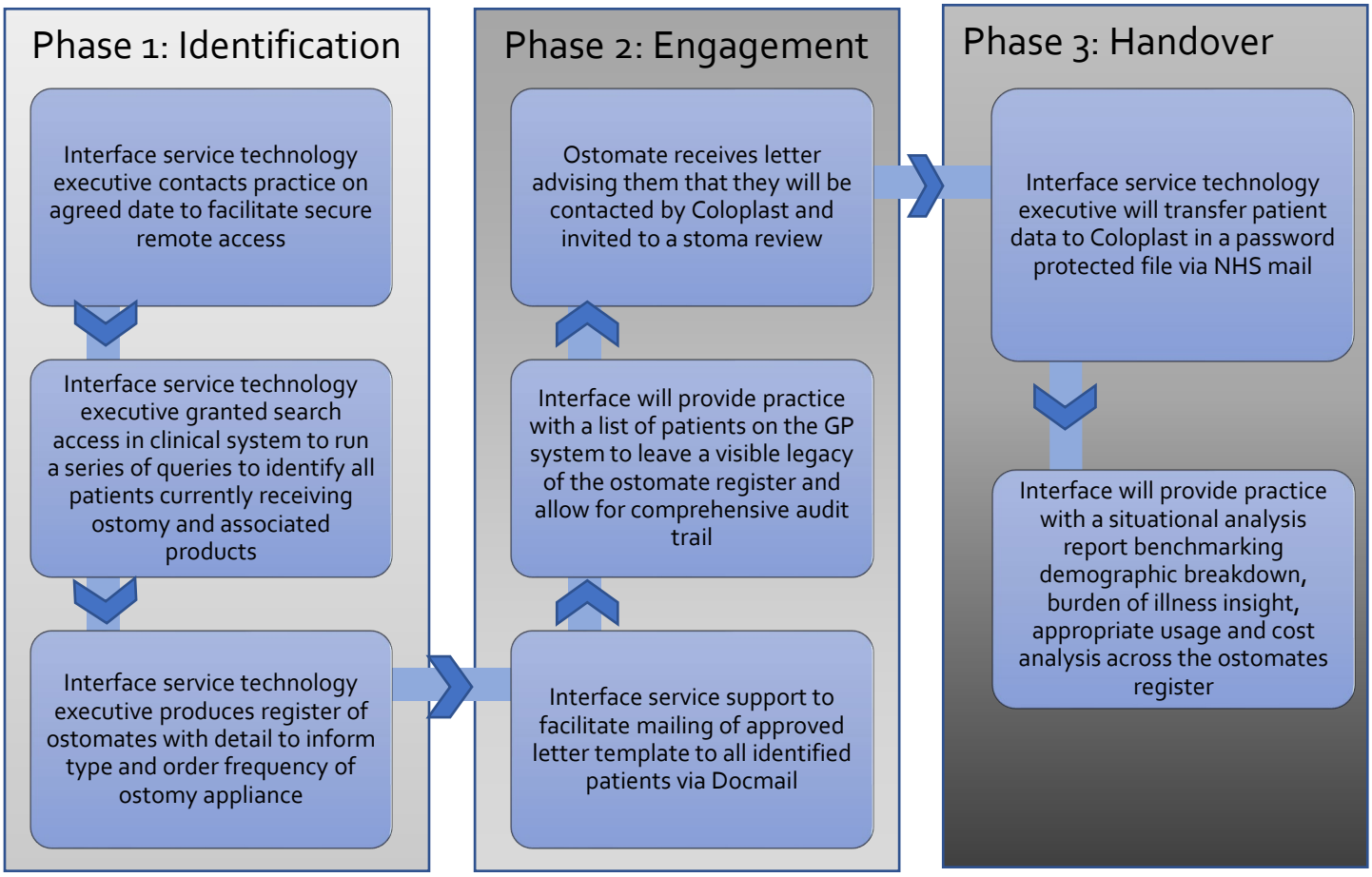
1.4 ACCOUNTABILITY AND MANAGEMENT

All Interface service technology executives have undergone a rigorous programme of training and are bound by an internal code of conduct covering confidentiality, information governance and ethics. In addition, Interface offer exacting standards of training and support to ensure safety and security across our platform of services including access to the HSCN NHS network with capacity to securely log in to Emis web and SystmOne through our own terminals.

Interface and Coloplast information governance policies are designed to align with wider NHS policy. Both organisations complete the Data Security and Protection (DSP) Toolkit, an online self-assessment tool that all organisations must use if they have access to NHS patient data and systems. It provides assurance that an organisation is practising good data security and that personal information is handled correctly, as well as allowing them to measure and publish their performance against the National Data Guardian's ten data security standards. Interface ensures that all working practices comply with the relevant data protection legislation.

The service requires a remote extraction of data which is extracted from the GP system by an Interface service technology executive using a pre-determined set of searches carried out via a secure encrypted connection.

SECTION 2: REVIEW PROCESS



SECTION 3 CONDUCT OF THE SERVICE

Interface must be in possession of a completed service authorisation form prior to commencement of any work. The authorisation form must be signed by the authorising GP prior to the commencement of any work.

The Interface service technology executive (STE) must be in possession of a current practice letterhead. This will be retained in order that it can be referred to at a later date.

For all remote dial-ins the STE will agree on a date and time with the GP practice.

The GP practice will setup Emis login details for the STE, or authorise their Smartcard for SystmOne, to ensure a traceable audit trail.

The STE will run a suite of queries designed to identify all patients currently receiving ostomy products on prescription, as well as reporting on key metrics to provide insight into the type and brand of ostomy product and quantity prescribed within the previous 12 months. Demographic information will be extracted to inform on the population dynamics in the context of age, gender and reason for stoma (i.e. indication/diagnosis) Additional markers will be analysed to inform on the current burden of illness and to highlight patients who may be experiencing problems. This initial insight report will be integrated with latest practice level prescribing data across the local health population to stratify practices according to clinical need in terms of average resource use per patient and overall number of patients identified.

Following the identification phase, the STE will prepare a mailing for all appropriate patients on behalf of the practice advising them that they will be contacted by Coloplast and invited for a review.

Letters will be sent out on the current GP practice letter head as provided by the practice. Unless otherwise specified by the GP, letters will be sent via the DocMail® communication platform to ensure that this phase is fully completed and to minimise the burden on the GP practice administration team. Clinic days allocated to each practice will be dependent on burden of illness defined by resource use and/or prevalence.

Any written materials, including patient education leaflets and template letters sent to patients, will be pre-approved by Coloplast.

The STE will provide Coloplast with data in order for them to contact the relevant patients. This will be sent in a password protected file, via NHS mail, and will contain patient name, NHS number, address, telephone number, date of birth and prescribing data.

The authorising GP or practice manager will be requested to communicate relevant information about the review to personnel within the practice (e.g. other GPs, receptionist, nurses) to ensure that patient queries can be dealt with effectively.

On completion of the dial-in, a patient list will be securely sent to the GP practice via NHSmail - this file should be saved in a secure location on the practice computer system. A summary dashboard will also be emailed to the key practice contact.

A courtesy email will be sent to the authorising GP to obtain GP practice feedback via an Interface web link to the satisfaction questionnaire.

STOMA PARTNERSHIP PROGRAMME

SERVICE AUTHORISATION FORM & DATA PROCESSING AGREEMENT

The service is designed to assist practices in implementing a systematic approach to the identification of ostomates across the practice population and to provide insight into the type, order frequency and cost of ostomy appliances and accessories.

The service also facilitates patient enrolment within the Coloplast Charter support programme, to allow patients to access tiered clinical support appropriate to their level of need.

DATA CONTROLLER

Practice Name:

Practice Organisation Code:

I authorise Interface Clinical Services Ltd. (Interface) and Coloplast Ltd to undertake the STOMA PARTNERSHIP PROGRAMME and accept full responsibility for communicating details of the service to all members of the Practice who will be affected.

I acknowledge and agree that I will retain responsibility and accountability for the service.

By signing:

- I confirm that I have read and understood the Stoma Partnership programme protocol.
- I understand that Interface and Coloplast will deliver separate parts of the programme and that neither organisation is accountable for the acts or omissions of the other party.
- I authorise Interface to remotely access the practice clinical system via a secure, encrypted connection and run, extract and collate data as required for provision of the service. The patient data identified by the remote searches can be transferred securely back to Interface systems for processing, but all identifiable data must be deleted from Interface systems within 10 days of service completion.
- I understand that the quality of the baseline report depends on the quality and completeness of our practice clinical data.
- I agree that, unless I specify otherwise, Interface will product a mail merge letter to all ostomates using the template letters in the protocol, which will be sent to patients via **DocMail®**. I agree to provide Interface with a copy of the practice letterhead.
- I agree to the Interface service support technician updating the patient's record in the clinical system with a copy of the letter sent.

I agree that Interface Clinical Services can provide a copy of patient data relating to the provision of the service to Coloplast via NHS mail. The data transferred includes: patient name, NHS number, address, telephone number, date of birth and prescribing data. ☐

NB: Once the practice has signed this form and ticked this box Coloplast will contact patients on behalf of the GP Practice to seek their consent to process patient data within their own systems as a data controller. Coloplast will then invite the patient to offer a stoma care review with a specialist stoma nurse. Coloplast will delete the copy of patient data provided by Interface within 30 days to minimise the risk of out-of-date data being used to contact patients. Data will not be disclosed to any other third parties or processed outside of the UK.

CLINICAL AUTHORISATION OF REVIEW

This section can only be signed by a GP who is a partner or employed by the practice who has the authority to sign on behalf of the practice.

I warrant that the practice as the data controller has a lawful basis to grant access to our patient data and that patient data can be processed by Interface as our data processor.

GP Signature:	
GP First Name:	
GP Surname:	
Date:	

DATA PROCESSOR AND SERVICE PROVIDER

The Data Controller wishes to formally appoint the following companies as Data Processors for the above service to ensure that Personal Data is processed in line with Data Protection Legislation.

1. INTERFACE CLINICAL SERVICES Ltd of Schofield House, Gate Way Drive, Yeadon, LS19 7XY, United Kingdom; Company number 6076464

2. COLOPLAST Ltd of Nene Hall Lynchwood Park, Peterborough Business Park, Peterborough, Cambridgeshire, PE2 6FX; Company number 01094405

This agreement sets out the Personal Data that the Data Processors shall process on behalf of the Data Controller, the purposes for which the data will be processed and the associated obligations of the Data Processors to ensure compliance with Data Protection Legislation.

Each Data Processor is separately accountable for ensuring that Personal Data is processed according to this agreement. Neither Data Processor is accountable nor liable for the actions of the other Data Processor.

DEFINITIONS

Data Protection Legislation means the Data Protection Act 2018 (DPA 2018), the General Data Protection Regulation (EU) 2016/679 (GDPR) and any applicable national laws implementing them, as well as the common law duty of confidentiality.

The terms **Data Controller, Data Processor, Data Subject, Personal Data, Personal Data Breach, Processing, Pseudonymisation, Special Categories of Personal Data** have the meanings that are defined in Data Protection Legislation.

Data Security and Protection Toolkit means the latest NHS Data Security and Protection Toolkit (or any future toolkit self-assessment format) that has been submitted prior to the date of this agreement.

1. DURATION

1.1 This agreement commences on the date this document is signed and shall terminate on completion of the service.

2. PERSONAL DATA PROCESSING

2.1 Details of the Personal Data and Special Categories of Personal Data that shall be Processed by the Data Processors under this agreement and the nature and purpose of the Processing are as set out in the schedule to this agreement. This agreement applies only to the data listed in the schedule.

2.2 The Data Processors shall Process that Personal Data only in accordance with Data Protection Legislation, and in accordance with the written instructions of the Data Controller unless required to do otherwise by law.
2.3 If the Data Processors are required by law to Process Personal Data otherwise than in accordance with the Controller's written instructions, each Data Processor shall notify the Data Controller of that legal requirement, unless the law prohibits such notification on important grounds of public interest.
2.4 The only sub-processor that Interface will use is CFH Docmail Ltd for patient mailings and permission will be sought from the practice for this.

3. CONFIDENTIALITY
3.1 All staff employed by the Data Processors have a contractual obligation for confidentiality.
3.2 All staff who access patient data have a Disclosure and Barring Service (DBS) or equivalent screening check upon commencement of employment and every three years subsequently. Any staff who have direct contact with patients have an enhanced screening check.
3.3 The Data Processors will have up to date cover of Employers Liability Insurance and Professional Indemnity Insurance, as required.

4. SECURITY MEASURES
4.1 The Data Processors shall implement appropriate technical and organisational measures to ensure a level of security appropriate to the Personal Data and the likely risks for the rights and freedoms of Data Subjects.
4.2 The Data Processors will ensure as a minimum, compliance with the security measures set out in the latest version of the Data Security and Protection Toolkit.
4.3 The Data Processors shall ensure that their employees do not process the Personal Data except in accordance with this agreement.
4.4 The Data Processors shall ensure that their employees are aware of and comply with this agreement, are informed of the confidential nature of the Personal Data, do not publish, disclose or divulge any of the Personal Data to any third party and have undergone adequate training in the use, care, protection and handling of Personal Data.
4.5 Devices used for remote access will be encrypted to NHS standards.

5. DATA PROCESSOR OBLIGATIONS
5.1 The Data Processors must assist the Data Controller should any Data Subjects exercise their rights under data protection legislation in relation to Personal Data being Processed under this agreement.
5.2 The Data Processors shall notify the Data Controller, as soon as reasonably practicable, about any request or complaint received from a Data Subject before responding to that request.
5.3 The Data Processors shall notify the Data Controller without undue delay if they become aware of a Personal Data Breach or suspected breach or if any personal data is or is suspected to be lost, corrupted, used or disclosed to a third party otherwise than in accordance with this section.
5.4 The Data Controller shall consult with the Data Processors before notifying the Information Commissioner and before notifying any Data Subjects about any such Personal Data Breach.

6. RETURN OR DESTRUCTION OF DATA
6.1 Within 10 days of service completion, all Personal Data will be permanently deleted other than any Personal Data that the Data Processors have obtained explicit consent from the Data Subject to retain as a Data Controller.

7. AUDIT
7.1 The Data Processors shall make available to the Data Controller information necessary to demonstrate their compliance with Data Protection Legislation.
7.2 At the Data Controller's cost, the Data Processors shall allow for and contribute to audits conducted by the Data Controller or its designated auditor.
7.3 The Data Processors shall notify the Data Controller if they believe any of the Data Controller's instructions infringe the Data Protection Legislation.

8. RECORDS OF PROCESSING
8.1 The Data Processors must maintain a record of all Processing activities carried out by or on behalf of the Data Controller including the categories of Processing and a general description of the technical and organisational measures.

9. VARIATION, FURTHER LEGISLATION AND GUIDANCE

9.1 No variation of this agreement shall be effective unless it is in writing and signed by the parties.
9.2 The parties agree to take account of any amendment to the Data Protection Legislation, and any relevant guidance issued by the Information Commissioner or the European Data Protection Board.

10. INTELLECTUAL PROPERTY RIGHTS

10.1 No intellectual property rights or obligations are granted or to be implied from this agreement.

11. CONFLICT

11.1 If there is an inconsistency or conflict between any of the provisions of this agreement and the provisions of any other agreement between the Data Controller and the Data Processors, the provisions of this agreement shall prevail in relation to Personal Data.

12. LIABILITY

12.1 The Data Processors shall not in any circumstances have any liability for any losses or damages that may be suffered by the Data Controller.
12.2 Nothing in this agreement excludes or limits the liability of either party for death or personal injury caused by such party's negligence, fraud or fraudulent misrepresentation or any other liability which cannot lawfully be excluded or limited.
12.3 Each party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misrepresentation based on any statement in this agreement.

13. GOVERNING LAW

13.1 This agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.
13.2 Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

SCHEDULE - DETAILS OF PERSONAL DATA PROCESSING

Subject matter of processing	Patient data records held in the healthcare organisation's system
Duration of Processing	Data will be processed from the start date of the service as documented in the service Authorisation Form until the service has been completed.
Nature/purpose of Processing	Personal Data is processed to provide a clinical review service for patients on behalf of the authorising NHS organisation. Services are designed to assist healthcare organisations implement systematic approaches to the health and wellbeing of patients with long term health conditions.
Categories of Data Subjects	Patients
Type(s) of Personal Data	Patient name and address; Demographic data; Health data
Retention of data	Within 10 days of service completion, all Personal Data will be permanently deleted other than any Personal Data that the Data Processors have obtained explicit consent from the Data Subject to retain as a Data Controller.

FOR COLOPLAST USE

Coloplast representative name		Expected # patients (prevalence %)	

Coloplast nurse name		Coloplast nurse email address	

Clinic Dates:					Nurse Led	
					Telehealth	