

# JOINT STATEMENT

On 31 October 2017 a meeting took place between Dr Corina van As-Brooks (Managing Director of Atos Medical UK and Countrywide Supplies Ltd), Kamini Gadhok (CEO, RCSLT), Dr Justin Roe (Chair RCSLT CEN Head and Neck Cancer South), Dominique Lowenthal (Head of Professional Development, RCSLT) and Sarah Orr (UCL Hospitals NHS Foundation Trust, representing BAHNON).

The meeting was to address concerns raised by members of the RCSLT CEN Head and Neck South and BAHNON. Atos Medical gave an explanation about the way it functioned and offered reassurances to RCSLT and BAHNON that it was operating strictly within a rigid legal framework and functioned no differently to other similar companies operating in the same medical field.

The meeting clarified the following key issues:

- Atos Medical AB acquired Countrywide Supplies Ltd in 2015. The merger triggered a formal investigation by the Competition & Markets Authority (CMA) which concluded that it did not reduce competition and therefore would not be referred under Section 22 of the Enterprise Act 2002.
- Atos Medical and Countrywide Supplies strictly enforce data protection rules and they conform to Information Governance level 2.
- Countrywide Supplies is committed to offering both the patient and the clinician the opportunity to access all products available on prescription from all suppliers, with an emphasis on the patient's individual needs. Countrywide Supplies holds a large inventory with products from all major suppliers and aims to deliver any appliance to the patient within 24 hours of receiving their prescription.
- Countrywide Supplies has a team of qualified nurses to provide Appliance Usage Reviews. These reviews are to ensure that prescribed appliances are used, stored and ultimately disposed of correctly. The services are only offered after a written agreement with the hospital (usually the Head and Neck MDT) is in place.

Although there was nothing to suggest that Atos Medical was behaving improperly or that its activities could interfere with the rights, privacy or medical interests of patients that it came in contact with, it was agreed that lack of communication around the merger, the company structure, and the implementation of the nursing service has led to misunderstandings.

With this in mind, it was agreed that Atos Medical and Countrywide Supplies would produce a FAQ document, flow charts and case studies which would fully explain how the company functions and how it connects with both patients and clinicians.

These documents are attached as Appendices to this joint statement:

- Appendix A: Frequently asked questions
- Appendix B: Case studies
- Appendix C: Flowcharts

To avoid any future misunderstandings and to ensure that members of BAHNON and RCSLT can address concerns and seek advice in a timely manner, Corina has acquired a secure nhs.net account and can be contacted directly at:

[c.vanas-brooks@nhs.net](mailto:c.vanas-brooks@nhs.net)

RCSLT CEN has also set up its own secure nhs.net address:

[rmh-tr.headandneckcen@nhs.net](mailto:rmh-tr.headandneckcen@nhs.net)

Please copy any correspondence that you feel would be relevant to other members to this address so that learning experiences can be shared with the wider membership when appropriate.

The meeting concluded that our organisations are all committed to ensuring the best possible care for patients in the spirit of transparency, collaboration and adherence to clinical governance principles.

January 2018

# Appendix A. Frequently asked questions regarding Atos Medical and Countrywide Supplies

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## What is the background of Atos Medical and Countrywide Supplies?

Atos Medical is a global company founded in 1986 in the south of Sweden. It has a direct presence in many countries, including the United Kingdom.

Atos Medical develops, manufactures and distributes products for laryngectomy and tracheostomy rehabilitation. The laryngectomy product range is known as *Provox* and the tracheostomy product line as *ProTrach*.

At the beginning of 2015, Atos Medical acquired Countrywide Supplies (CWS Ltd), and the companies now operate within the UK as a single legal entity.

The companies acknowledge that at the time of the merger, as well as thereafter, the relationship between them has not been communicated as clearly as it could have done to all stakeholders.

The merger of the two companies was thoroughly investigated by the Competition & Markets Authority (CMA). The conclusion of the CMA investigation was that the merger has not resulted, or may not be expected to result, in a significant lessening of competition (SLC).

A full report of the CMA investigation is available at <http://tiny.cc/atosmedical>.

It is common within the UK market for manufacturers to own and operate prescription and home delivery services. In fact, nearly all of the Dispensing Appliance Contractor (DAC) licenses are owned by trans-national medical device companies. This practice enables the manufacturer to provide products (all those that are available on prescription, thus their own and other manufacturer's) directly to consumers at a local level – improving efficiency and the level of service which benefits the user.

## What is the Atos Medical/CWS strategy?

Atos Medical pursues a strategy of empowering its end-user. At all levels of the company staff are continually encouraged to put them at the centre of everything that they do. This strategy of empowering end-users permeates every part of the company and its activities.

Like any successful medical company, Atos Medical invests a significant amount into research and development and its profits are no greater than comparable companies.

Services including community events, nurse visits, and order reminder calls, texts, or emails, are all designed to connect with its customers directly and ultimately improve the end-users' compliance with the prescribed treatment, which is of benefit to the patient and the clinician.

## **What is a DAC?**

CWS is what the NHS terms a Dispensing Appliance Contractor (DAC). This means that it distributes prescriptions in a similar way to a high street pharmacy.

And like a pharmacy, CWS has to conform to strict standards and regulations which govern the way it operates, and, crucially, the way it protects sensitive patient data.

In practical terms, being a DAC means that as well as dispensing appliances it is obliged to support self-care, promote healthy lifestyles, exhibit clinical governance and advise on the utilisation, storage, and disposal of appliances.

CWS is contracted to provide advanced services as an NHS contractor. Part of this means there is an expectation that CWS will give all of their customers the opportunity to have an appliance usage review (AUR) should they wish.

CWS specialises in servicing head and neck patients.

## **What is an AUR?**

CWS offers appliance usage reviews (AURs) which are carried out by qualified nurses. This can take place in a pharmacy or at the patient's home and is designed to improve their knowledge of the appliances they have been prescribed.

Nurses and other staff who directly support customers undergo intensive and continual training to ensure that they can provide the best service available.

As well as establishing how the appliance works, AURs also educate the patient in how the appliance can be used most effectively, how it should be stored safely and its ultimate disposal.

The performance of AURs is strictly controlled and CWS's nurses are prohibited from promoting Atos Medical products. The AUR covers the appliances that the patient has been prescribed. Any changes to appliances used must be directed by the relevant hospital team. The CWS nurse will not change any product without prior agreement from the hospital.

## **How does the CWS nursing service form a new relationship with a trust or hospital and how do they work with the MDT?**

Initially, the CWS nurse and/or nurse manager will visit the ENT/Head & Neck team, to explain what its services are and discuss whether it is something that the hospital team would find helpful to their patients.

Once a trust or hospital has indicated to be interested in this service for their patients, further details are discussed and agreed. This verbal agreement is confirmed via email, and if required a 'share care' agreement or honorary contract is put in place.

The agreement is adapted to the hospital preferences and needs, and covers for example which patients will be offered the service, and who will contact them.

The CWS nursing service intends to collaborate with the local MDT. For example, the CWS nurse will always inform the responsible clinician of the nurse visits planned, send a copy of the AUR form for the visit, and offer regular reviews with the MDT or responsible clinician.

## **What training do CWS nursing and customer care staff undergo?**

CWS nurses are rigorously screened for experience and suitability for the role of head and neck specialist nurse.

It is a requirement that CWS nurses all have prior experience in this area. Prior to seeing any patients, the nurse undertakes a three-week induction programme which includes face-to-face training as well as online training, including the Imperial College Head and Neck course. Each nurse is fully qualified and registered, has an active PIN and has enhanced DBS clearance. Prior to seeing patients independently, the nurse shadows the established nursing team.

The nurses also undertake regular continuing education and clinical supervision.

The CWS customer care team undergoes a two week intensive initial training and induction before they speak to patients, as well as continuing clinical and product training by qualified HCPs.

Despite CWS's investment in training for its staff, as well as rigorous policies and procedures, occasional errors or mistakes can happen and CWS wants to hear about them right away.

If CWS receives complaints or concerns it will immediate review and take action where appropriate.

## **How does patient consent work within CWS?**

CWS has a firm commitment to patient privacy and ensuring that it uses patient information only as necessary and for a clear legal purpose.

CWS's relationship with patients is underpinned by its absolute requirement for patient consent and, where appropriate, ensuring that clinicians have consented to transfer patients' information.

In practical terms, this means both a local consent and a CWS consent are obtained from every patient.

As with any company, CWS is legally required to obtain the consent of the patient before collecting and using their personal information.

This means that CWS explains to patients what it will use their information for and ask their permission to do so. CWS will also make patients aware that they can change their mind about this consent at any time.

CWS has a rigorous process in place for gaining consent and ensure that everyone in the company understands and adheres to this process.

CWS believes in a personal level of care, which means that each patient decides on how the company will provide services to them. For instance, how they like to be contacted, whether they will receive news on products and services and how often they would like to receive reminders to order the products that they need.

### **What is CWS's approach to data and information governance?**

All UK-based Atos Medical and CWS staff are employed by the same company, which is CWS Ltd. Patient data is only shared between employees, and only when absolutely necessary; it is not transferred between different organisations

In compliance with the seven Caldicott principles, information sharing is strictly monitored by the CWS-registered Caldicott guardian to ensure that not only does CWS operate lawfully but ethically as well.

The Atos Medical group has access to anonymised patient data which is only used for data analysis purposes.

The supply of any medical service must be underpinned by a need to protect patient confidentiality and CWS is fully compliant to Level II of the Information Governance (IG) requirements as defined in the NHS guidelines.

CWS is currently in process of finalising a submission for Level III compliance. All CWS employees carry out regular IG updates as well as data protection training.

Whilst not required by law, CWS has chosen to undertake registration with the CQC to emphasise its commitment to providing a safe, ethical and quality service.

As a manufacturer and distributor of medical devices, the Atos Medical Group also complies with all relevant regulations; Atos Medical and CWS in the UK are currently conducting a Privacy Impact Assessment in preparation for GDPR 2018.

## How does CWS carry out marketing?

CWS only promotes products and services to customers that have indicated that they are interested in receiving such information and have given their consent. The customer will only receive marketing information about products that are relevant to their condition and current product usage, and about services that are relevant and available to them.

Examples of marketing information include newsletters, e-mails, brochures and flyers about products and services. Marketing materials going out to patients always include a phrase to check suitability with their clinician e.g. 'as always, talk to your clinician about which products are right for you'.

In addition, CWS representatives will always aim to check with the patient's responsible clinician or prescriber when new products or samples are requested that require assessment of appropriateness by their responsible clinician or prescriber.

CWS will always aim to inform clinicians about new products first. Should any clinician feel they are not on our mailing list but would like to be, please contact [marketing@atosmedical.com](mailto:marketing@atosmedical.com).

## What process does CWS follow when a patient wants to try a new product?

CWS provides the appliances that are on the patient's prescription. It is CWS's process that if a patient wishes to change their product, or sample a new product, they should first discuss this with the responsible clinician or prescriber. When the patient requests a product or sample that requires assessment of appropriateness by the responsible clinician or prescriber, the CWS representative will discuss the request directly with the responsible clinician or prescriber, on behalf of the patient.

## What products are provided via CWS?

CWS is committed to offering both the patient and the clinician the opportunity to access all products available on prescription from all suppliers, with an emphasis on the patient's individual needs. CWS holds a large inventory with products from all major suppliers and aims to deliver any appliance to the patient within 24 hours of receiving the prescription.

All products dispensed by CWS that are prescribed for each patient, are on the Drug Tariff and are brand specific on the prescription. If a patient would like to try a new product, CWS will always check suitability and discuss with the responsible clinician or prescriber first when an assessment of appropriateness is required.

If a product is unavailable, CWS can provide an alternative but again will always check with the responsible clinician or prescriber unless it concerns an accessory where the difference between brands or products is negligible and an assessment is not required.

## **Can you tell us more about the Atos Medical community events?**

In support of their user-driven innovation strategy, Atos Medical commissioned an anthropological study together with Red Associates.

In addition to identifying user needs requiring product innovation, this work revealed a large number of unfulfilled user needs that can be met with services and education. For example, people with a laryngectomy would like to feel more knowledgeable about their changed anatomy and increase their product literacy.

As a result of this, the Atos Medical Group has initiated community events for people with a laryngectomy and their spouse and/or caregiver. The events are designed to be small (approximately 4-6 per event), educational and informative, and encourage engaging discussions around key topics such as 'staying active' or 'better sleep'. They are also local and informal to ensure attendees can access the venues easily and meet other users in the local community. The events are usually held in venues outside of the hospital environment allowing users to feel relaxed and have a sense of normality. In some cases the events are held at a hospital.

In some areas in the UK these community events have been inadvertently initiated without informing the clinical community, and clinicians may have been unaware of the anthropological study results that have led to these events. Atos Medical has taken steps to ensure that this should not happen again.

These community events are open to all people with a laryngectomy, regardless of their service provider or product used.

Atos Medical encourages the HCPs to be involved with these events, and although clinic time may not always permit attendance, clinicians are always welcome to attend. Similarly, Atos would like to collaborate more with the clinical community and our Managing Director Dr Corina Van As Brooks is keen to join upcoming CEN meetings to share the background of the anthropological study that led to the creation of community events.

## **How can someone make a complaint if they are dissatisfied?**

If you have any questions or concerns in relation to CWS please contact your local CWS and Atos Medical representative or email [info@countrywidesupplies.co.uk](mailto:info@countrywidesupplies.co.uk).

If you would like to talk to the Managing Director directly you can contact her on [Corina.van.As@atosmedical.com](mailto:Corina.van.As@atosmedical.com) or, for correspondence containing patient data, on [c.vanas-brooks@nhs.net](mailto:c.vanas-brooks@nhs.net).

General enquiries and any lessons learned that may be relevant to the wider membership of the CEN can also be sent to Corina [c.vanas-brooks@nhs.net](mailto:c.vanas-brooks@nhs.net) with a copy to the RCSLT CEN [rmh-tr.headandneckcen@nhs.net](mailto:rmh-tr.headandneckcen@nhs.net).

# Appendix B. Three case studies from the Countrywide Supplies nurse service

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## Case 1. 'Ben'

**Ben was a newly laryngectomised patient who was due to be discharged home but was feeling increasingly anxious about the challenge of adjusting to the outside world. Both Ben and his wife were apprehensive about the level of support that they had been receiving in the hospital and had doubts about how much assistance they would receive once he was in the outside world.**

As a consequence of these concerns, Ben's SLT contacted the CWS nurse to ask whether Ben could receive additional support. There was also a concern that Ben and his wife were struggling to comprehend all of the additional information that they had been given. Prior to his discharge, the CWS nurse and the SLT met with Ben and his wife and it was explained that he would be given support until he was established at home and comfortable caring for his new laryngectomy and comfortable using his appliances at home.

On returning home for the first time, Ben was concerned that he would not be able to carry out self-care for his stoma and voice prosthesis. The CWS nurse visited on the same day and spent a long time with Ben and his wife ensuring that they understood how the self-care regime worked and how it should become a normal part of their daily routine. The nurse talked them through the contents of the box of appliances and addressed all of their concerns. The plan of care implemented by the SLT was explained and emphasis was placed on the importance of following the prescribed care pathway.

Over the next two weeks, the CWS nurse visited Ben on five occasions to provide the necessary support and to ensure that he was confident with the use of his appliances. Each the nurse provided the couple with more information, background as to why he had been prescribed the products as well as emphasising the importance of HME use and why it was important for his pulmonary health. Although Ben had been given all of this information while he was in hospital he had found it difficult to remember many of the details.

At the end of this process, Ben and his wife said that they were comfortable with giving self-care and understood why following the prescribed care pathway was important for his rehabilitation and health. Throughout the process, the nurse liaised closely with the SLT, by both phone and email, and always returned the completed documentation.

At Ben's first SLT outpatient appointment, the SLT said that they were "really pleased" with his progress. His voice prosthesis was clean and well cared for, his skin integrity was good, and he had healed well and was ready to progress to the next stage of his rehabilitation. The SLT also suggested that had the CWS nurse not provided this level of support and assistance, there was a serious risk that Ben would have had run into difficulties, largely as a consequence of his lack of confidence about how to care for his stoma and voice prosthesis.

This collaborative approach with the CWS nurse providing support for the SLT clearly resulted in a faster and safer adjustment for Ben to life as a laryngectomee.

## Case 2. 'Jim'

**Jim has lived with his laryngectomy for 12 years. He no longer has a voice prosthesis insitu due to co-morbidities which have affected his tissue integrity. Jim speaks with an electrolarynx and has struggled with excess secretions, frequent chest infections, shortness of breath and rarely left his house.**

Eight years ago Jim and his wife relocated to a different part of the country and there was no transfer of his case to the local ear, nose and throat team. He had been using a saline nebuliser four times daily, which had not been serviced in seven years and he did not use any appliances.

Jim requested a visit from the CWS nurse to see whether they could offer any advice to help him with his excessive secretions.

At the first visit, the nurse listened to Jim's story and history, including how isolated he felt. Jim explained that his GP surgery did not understand his laryngectomy needs and he had little confidence in them. He was also embarrassed even to go outside due to the obvious stoma entry in his neck, did not use any appliances and had no understanding about products.

The nurse then explained to Jim and his wife the products that were available to him, what they did, how they work and why it was important to maintain a healthy airway.

The nurse left samples of different base plates and heat and moisture exchangers (HMEs) and demonstrated to Jim how to use them. She emphasised that he would see an increase in secretions and coughing and that it was to be expected but that it would ease after several days. The nurse also explained that he might find breathing difficult through a HME to start with and how he may need to gradually build up his use. The nurse left her contact details and agreed to return in a week.

The second visit, the nurse arrived to find Jim proudly wearing his favourite HME and base plate. He reported that he felt good and that everything had happened as the

nurse had explained. He had gradually built up his breathing resistance and had experienced increased secretions and coughing for around four days and said that he had nearly given up, but persevered. Jim was excited that he had not needed to use his nebuliser at all after the first four days and this was a breakthrough for him as he did not like feeling tied to it.

Although he still felt uncomfortable speaking in public with his electro larynx, he did not mind going out now, because he had something covering his stoma and felt less self-conscious.

Jim explained which products were the ones he preferred to use and enquired if there was anything he could use to enable him to wear a HME when he wanted to rest his skin. Buttons and tubes were discussed and sized.

More visits took place over the next two months to ensure that Jim and his wife were comfortable with the products and felt that they are being supported.

The CWS nurse had suggested that Jim might benefit from a new referral to his local ENT team for review, but Jim declined as he did not want further surgeries and was not fond of hospitals.

Five months after the initial visit by CWS, Jim has reported that he has now felt confident enough to build a shed in his garden, cut the grass and had even acquired an exercise bike. His breathing was now considerably better than it had been for many years. His wife reported that he was sleeping better and his energy levels were increased.

### **Case 3. 'Tom'**

**'Tom' had requested a home visit from a CWS nurse. Tom had non-indwelling voice prosthesis insitu and had not been seen by his SLT for some time as he was managing his care independently. As Tom's hospital had agreed to the CWS nurse service for their patients, the SLT was informed of the home visit request by the CWS nurse and a home visit was arranged.**

When the nurse visited, Tom explained that his stoma had been gradually getting smaller and he was now struggling to clean his voice prosthesis effectively. After examining his stoma the CWS nurse contacted the SLT by telephone to explain about the reducing stoma size and establish what the SLT would like to do. The SLT requested that Tom attend clinic at the earliest possibility, but Tom was unwilling to re-visit the hospital due to other commitments he had. The SLT and CWS nurse discussed the options that were available to help Tom without him attending the hospital. The SLT

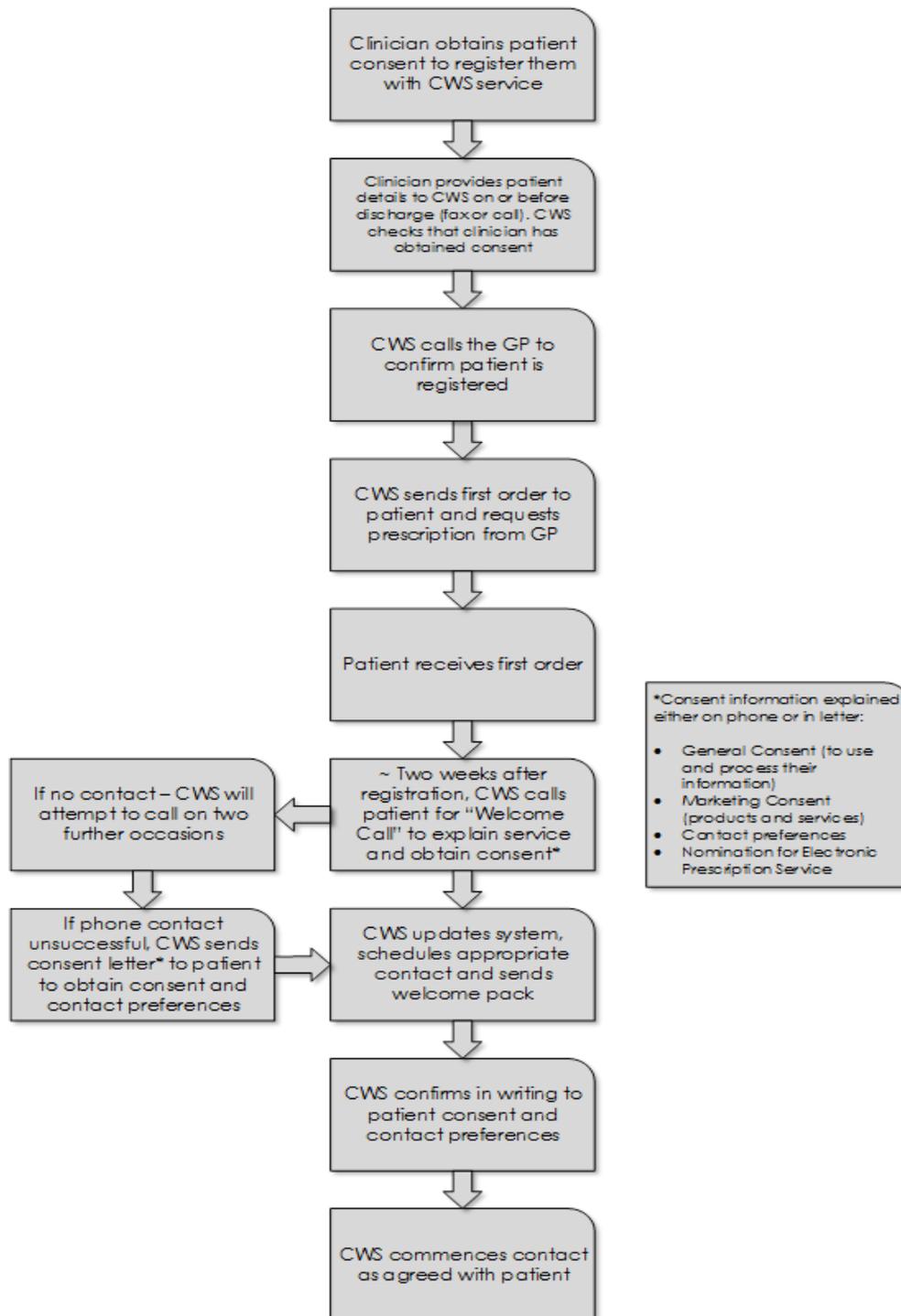
requested that the CWS nurse re-visit Tom and try to fit a stoma button, to attempt to maintain the stoma until he could be seen by the hospital team.

The CWS nurse then fitted the patient with a stoma button and advised the patient that the SLT needed him to attend clinic and explained the importance of following the SLT request. Once again Tom declined to attend, but said that he would use the stoma button. The CWS nurse showed Tom how to insert, remove and clean the button. Following the visit, the CWS nurse informed the SLT and a copy of the documentation was emailed by NHS.net to the SLT for hospital records.

The SLT and the CWS discussed the risk involved of Tom not attending the clinic and it was agreed that the SLT would contact Tom directly. Despite this, Tom still declined to change his plans and chose not to attend the hospital. The SLT discussed with the CWS nurse and they both agreed to the CWS nurse making a final visit to reiterate the importance of hospital attendance.

At the final visit, the CWS nurse explained the rationale for wanting Tom to attend clinic and why both the SLT and CWS nurse were concerned. Tom continued to decline a clinic visit; however with the CWS nurse available to work collaboratively with the hospital SLT, Tom's problem was resolved. Appropriate documentation was completed showing details of the conversations and collaborative working which identified the intervention attempted by both the CWS nurse and the SLT, ensuring that they had both fulfilled their duty of care.

# Appendix C1. Flowchart CWS patient registration journey



## Appendix C2. Flowchart CWS nurse service.

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