FACEREMELIUS

UNDER STRICT EMBARGO UNTIL 5PM ON 17 SEPTEMBER 2020

INDEPENDENT INVESTIGATION

into the care and treatment of the individuals who contracted invasive Group A streptococcal (iGAS) bacterial infection during the mid and west Essex outbreak, and subsequently died

June 2020

Section 1: Contents

Section 2: Introduction

In February 2019 Public Health England identified an outbreak of an invasive Group A Streptococcus bacterial infection (iGAS) that had affected a number of people in the Mid Essex area. Thirty-nine people were infected, of whom thirty-three were confirmed from blood tests to be part of the iGAS outbreak, with a further six probable cases. Fifteen of those involved in this outbreak and affected with this infection have died. Of these, two have not been reviewed as part of this process, one because of lack of available information, and the other because that person's death occurred after this process had started. Another twenty-four patients contracted the infection and survived.

Invasive Group A streptococcal (iGAS) infection is rare, but serious, and sudden local increases in a disease such as this can sometimes occur. The increase in the number of cases in Essex was considered serious; tests were able to identify the particular strain (emm44), and confirm that the cases were linked. This led to the understanding that this was an outbreak situation, and not a series of isolated cases.

Mid Essex Clinical Commissioning Group (MECCG) commissioned an independent investigation into this outbreak. This is in line with the national guidance on Learning from Deaths (July 2017 and 2018) and the NHS England Serious Incident Framework (March 2015). The purpose of investigations under these frameworks is to learn from the care provided to patients who suffer harm, to support learning, and reduce the likelihood of similar events happening again:

Investigations carried out under this Framework are conducted for the purposes of learning to prevent recurrence. They are not inquiries into how the person died, as this is a matter for the coroner. Neither are they conducted to hold any individual or organisation to account. Other processes exist for that purpose, including criminal or civil proceedings, disciplinary procedures, employment law and systems of service and professional regulation… In circumstances where the actions of other agencies are required then those agencies must be appropriately informed and relevant

protocols outside the scope of this Framework must be followed (NHS England Serious Incident Framework 2015, appendix 3: Independent Investigation (level 3)).

In July 2019 the MECCG director of nursing formally commissioned Facere Melius, a healthcare consultancy, to undertake individual reviews into thirteen cases where death occurred, and twenty-four survivor cases, which would in turn form the basis of the independent investigation report. In November 2019 following a 'pause' requested by NHS England, the terms of reference were revised; work was suspended on all the survivor cases and these cases were then excluded from the commissioned programme. The programme then resumed and was undertaken in two stages:

- Stage 1: focused on an individual review in the form of a patient story for each of the thirteen patients who had a confirmed or probable case of the iGAS infection and subsequently died. The review explored the care and treatment they received and identified any individual learning for the organisation(s) involved in each case. Each family who wished to be involved in the investigation will receive an individual report about their relative's circumstances and key findings specific to their care.
- Stage 2: an independent investigation report. This investigation has analysed and summarised the service delivery problems and contributing factors from each individual review, and correlated these findings to provide the collective learning from all the reviews of cases in which someone died. This report has identified any wider themes and points of learning, and made implementable recommendations in order to reduce the risk of recurrence.

Section 3: Investigation process and methodology

As mentioned in section 2 above, the investigation has been undertaken in accordance with the national guidance on Learning from Deaths and the NHS England Serious Incident Framework.

The framework also states that *it is fundamental that the patients/service users and/or family/carers are involved from the very beginning of the process and that their needs are assessed to ensure they are appropriately supported... (*NHS Serious Incident Framework, p.63).

3.1 Terms of reference

The revised terms of reference were agreed with the CCG and approved by the Mid Essex incident management team in November 2019.

3.2 Investigation team

- Nine Facere Melius associates (reviewers) undertook the individual reviews that have contributed to the independent investigation report
- Facere Melius's senior oversight team led and coordinated the individual reviews; this team then collated the key findings and themes from those reviews for the independent investigation report.
- The Facere Melius clinical advisory board consisted of the senior oversight team and the following clinical advisers, who provided additional support, specialist guidance, analysis and expert opinion:
    - Executive director of nursing
    - Executive medical director
    - Consultant microbiologist
    - Tissue viability specialist
    - Community infection control specialist

3.3 Methodology

3.3.1 Individual cases

For each of the thirteen individual cases the review team used a range of both

quantitative and qualitative techniques to undertake the review. The team had access to and consulted 1,756 documents, which included:

- Medical and clinical information relating to each of the thirteen patients
- Structured judgement reviews (SJRs) undertaken by Provide Community Interest Company and Mid Essex Hospital Trust
- National policies, guidelines and protocols
- Local policies, guidelines and protocols from various stakeholder organisations involved in the individual reviews
- Minutes and notes from internal organisational meetings
- Internal communications on the outbreak
- Correspondence from MECCG to the bereaved next of kin

All the relatives of those who had died were contacted and invited to meet with the team to contribute to the review. Five of them met with reviewers in November 2019, two spoke to them by telephone, and a further two requested a copy of their relative's story.

In November and December meetings took place with 34 members of staff from Provide Community Interest Company (CIC) and Mid Essex Hospital Trust. These meetings were with members of staff who were either directly involved in the care of the deceased patients, or had a clinical leadership role within the organisations. Further meetings took place via telephone calls/teleconferencing and written responses to questions with GP services, care homes and East of England Ambulance Service, where there had been involvement in the care of the deceased patients.

Following the document reviews and meetings with relatives and staff, the review team verified the chronology of events for each individual patient and identified key themes and findings in each case. These were rigorously analysed, assimilated, fact checked and verified. Each individual report was then drafted and quality assured by the Facere Melius clinical advisory board.

These reports were then sent to the MECCG for a factual accuracy process. Once this was complete, MECCG, in line with duty of candour regulations, will make

arrangements to share with each family (who wished to be involved) the report into the care and treatment of their relative who contracted the iGAS infection, and subsequently died.

3.3.2 Independent investigation and report

The purpose of this independent investigation, and the report arising from it, as stated above, is to identify the key themes and collective learning from the thirteen individual reviews. The findings from these reviews were based on the information which the Facere Melius review teams were provided with and had access to. The focus of this independent investigation and report is to identify implementable recommendations to reduce the risk of recurrence. Its methodology followed a similar process to the individual reviews, using both quantitative and qualitative techniques to undertake the investigation. This included an analysis of the findings from the individual reviews to identify the collective themes emerging.

Where illustrative examples in this report are cited from the thirteen individuals' stories, the identity of each individual has been anonymised by using a random letter of the alphabet instead of their name.

Section 4: Context

Mid Essex covers three main localities: Braintree District, Chelmsford City and Maldon District, an area of approximately 520 square miles, with a population of around 379,000 (Public Sector Equality and Diversity report 2015). A number of organisations were involved in the incident regarding the outbreak of an invasive Group A streptococcal bacterial infection (iGAS) that had affected a number of people in the Mid Essex area. These included:

- Healthcare providers
    - Acute (hospitals)
    - Community care
    - Primary care
    - Ambulance service
    - Out of hours/NHS 111 service
- Clinical commissioning groups
- Domiciliary care providers
- Adult social care services
- Nursing and residential homes
- Local authority public health teams
- National bodies

Eight of the GP practices in the area which provide primary medical care had one or more patients involved in the outbreak who subsequently died; five care homes providing a range of residential and nursing services had a resident or residents who contracted the iGAS infection and subsequently died.

4.1 Background

Those individuals who are the subject of this report and who were affected by the iGAS outbreak and subsequently died were elderly people living in these localities. Their ages ranged from 76 to 95; nine were female and four male, all of whom died in the period January - July 2019. In all but one case, they were receiving treatment

for wounds and had one or more additional conditions co-occurring with a primary condition, known as co-morbidities; seven were living in their own homes; six lived in care homes.

Provide CIC nursing team, known as the integrated care team (ICT), were delivering treatment for wound care for all but two of the individuals. One person was receiving treatment from Essex Partnership University Trust (EPUT) community nursing team; the other person did not have any wound treatment. Twelve people died in Mid Essex Hospital Trust (MEHT) - Broomfield Hospital, and one person died in East Suffolk and North Essex NHS Foundation Trust - Colchester Hospital.

4.2 iGAS outbreak

On 12 March 2019 Public Health England established an incident management multi-agency team. In late May the leadership of this team transferred to Mid Essex Clinical Commissioning Group (MECCG). This team worked closely together to ensure all efforts were made to control the transmission of invasive Group A streptococcal infection (strain emm44), and to prevent more people becoming infected. Since August 2019 no further cases have been identified. In January 2020 the MECCG along with the partners involved in the incident management took the decision to step down the incident management team and some of the control measures that had been in place since March 2019.

Public Health England (PHE) has responsibility for preparing for and responding to public health emergencies such as this outbreak. In July 2019 they undertook Whole Genome Sequencing (the process of determining the complete DNA sequence of an organism's genome at a single time) to investigate differences and similarities in the DNA sequence of the iGAS bacteria collected from patients within the Mid Essex outbreak. By analysing the DNA sequencing of each bacterial sample, PHE was able to confirm which iGAS cases were genetically linked and which were not. This process excluded another two cases (one in Basildon in 2018 and one in Southend in February 2019) thought initially to be part of the Essex outbreak, bringing the deaths

relating to this outbreak to fifteen. As noted in section 2 above, this independent investigation does not include two of the cases where the individuals died.

Although PHE has conducted an epidemiological investigation into the outbreak, that investigation did not assess the quality of care given to those people who contracted the iGAS infection. This led to the MECCG's decision to commission an independent investigation into the care of the deceased patients and to identify the collective learning to reduce the risk of recurrence.

4.3 Group A streptococcal (GAS) and invasive Group A streptococcal (iGAS) bacterial infections

Group A Streptococci, (GAS), are bacteria most commonly found in the throat and on the skin and will not cause any illness for the majority of people. Some GAS infections can cause a variety of illnesses, including a sore throat and skin infections. For most healthy people this will cause no more than a mild illness that can be treated with antibiotics. However, on rare occasions, this bacterium can enter the body and cause severe and sometimes life-threatening conditions. This is called invasive Group A streptococcal disease – iGAS. Elderly people, or those whose immune systems are compromised, are at particular risk.

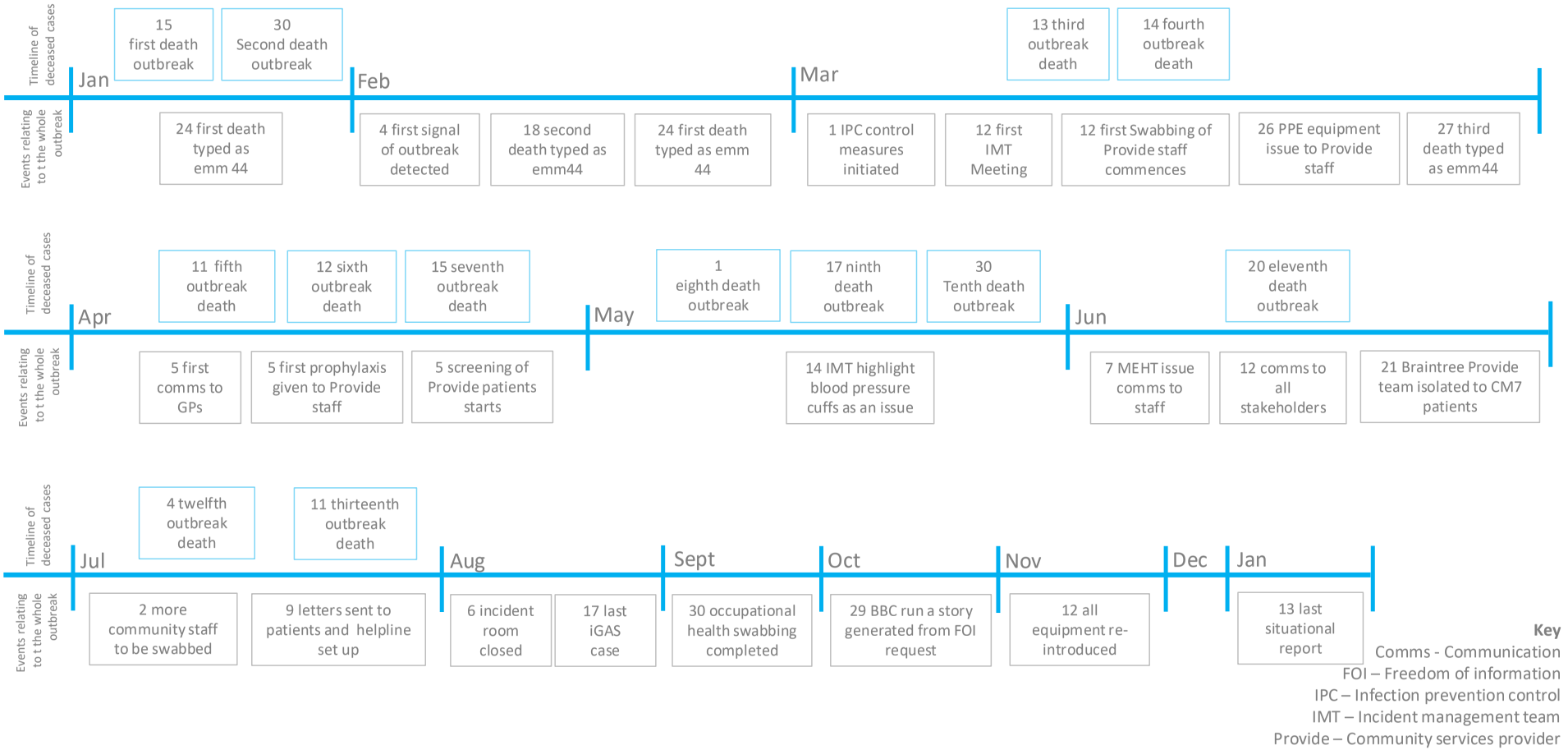
Group A streptococcal (GAS) infections can be detected from the results of wound swabs, whereas iGAS can only be confirmed from the results of a blood culture and tissue samples, analysed in a laboratory; this process can take at least 48 hours. iGAS can become potentially lethal and trigger sepsis and toxic shock. When clinical signs indicate the presence of sepsis, antibiotics are prescribed. If an iGAS infection is then confirmed with the bacteria type, the antibiotic prescription can be refined. Cases of iGAS are classed as a notifiable disease and Public Health England must be informed of new cases. Although an outbreak of this size is rare, iGAS has been seen before in the UK, in 2018 there were 2880 cases.

4.4 Timeline

The following graphic represents the timeline of the thirteen people who contracted iGAS strain emm44 and subsequently died, alongside key events related to the entire outbreak.

Timeline

The following graphic represents the timeline of 13 cases that subsequently died alongside key events relating to the whole outbreak in 2016



Section 5: Key themes arising from the thirteen cases

The cases of the thirteen individuals who died in hospital after contracting the emm44 strain of iGAS, from which these key themes were collated, represent a subset of the entire group of people who contracted this same infection during the outbreak. There was a slightly larger group of people who contracted the infection, and who survived; as stated above, this set of people was not included in the scope of this investigation. Therefore the themes and findings detailed below only relate to the care and treatment of the thirteen individuals reviewed:

- Wound management in the community
- Wound management practitioners/training/competency
- Wound management in hospital
- Identifying clinical deterioration
- Antibiotic therapy
- Infection prevention and control
- Record keeping

The Facere Melius review team produced individual reviews for each of these thirteen individuals. Each review assessed the key clinical events in the individual's care in the community, and subsequent treatment after their final admission to hospital. The review team had access to various documents, including national guidelines and policies, and had meetings with a number of staff with organisations involved in the thirteen individuals' care. The findings in the report are limited to the information available, and the people the team were able to speak to.

The findings from the thirteen reviews have been collated to identify key themes, and to bring together any learning from the care and treatment of those individuals who died after contracting the outbreak strain of iGAS. Some were also receiving support from other community nursing services, such as for catheter care, and for other medical conditions, such as lung disease, Parkinson's disease and dementia.

As noted above, all but one of the individuals were having treatment from primary care providers, supported by community nursing services (Provide and EPUT), for skin/pressure ulcers or other kinds of wound. Two had regular care arrangements to provide support for daily living tasks and personal care. Six were receiving personal care in the care homes where they lived. All thirteen had a final admission to hospital (twelve in Broomfield, one in Colchester), where they received care and treatment prior to their death. The length of time they spent during this final period in hospital ranged from a few hours to nearly three weeks.

The majority of care received by individuals was in accordance with local guidance; however, several important areas were found where learning has been identified and improvement can be made.

5.1 Wound management in the community

There are occasions across the cases when the clinical practice was not always in accordance with the standards and general principles set out in the local guidelines on the management of wounds and/or pressure ulcers. These related to areas such as undertaking holistic initial assessment, clear recording of the description of the wound, measurement, photographing/tracing and recording of wound size, and taking bacterial wound swabs when there was an indication of clinical infection. These are all areas where improvement in timely implementation of consistent and recognised best practice should be striven for, in order to provide good patient care.

Example 1

… clinical notes do not record that a baseline assessment of [person D's] wounds was undertaken. This would usually have included photographs and a description - size, etc. It would thus have provided a baseline from which to monitor progress or any deterioration.

Example 2

… wound care plan was based upon incomplete information, which meant that those treating [person A] did not have a clear clinical picture of [the] wound when it deteriorated – for example, photographs and measurements of size of the wound over time were not recorded…Baseline observations, wound type and cause were also not recorded. Subsequent visits were carried out on the basis of this partial information, and care at this time was inconsistent; for example, over seven visits, five different types of dressing were recorded as applied to A's wound, of which three were not appropriate for the wound as described.

For some of those receiving treatment it is evident that monitoring of the deterioration of the wound and/or escalation for senior advice or referral for specialist advice did not happen in a timely manner.

Example 3

For some considerable time [person T's] wound was not improving, and the ICT were unable to identify a course of dressings that was both clinically suitable and acceptable to [T], given [their] preference for the [special type of] dressings. Such a situation should have been escalated to a senior team leader, or referred to the tissue viability service for specialist advice on treatment options.

Example 4

[Person E's] wound continued to deteriorate over a period of 22 days and a referral to the tissue viability service for advice on treatment might have been appropriate.

From discussions with staff and review of minutes of meetings it would appear that this non-escalation of deteriorating wound conditions may have been partly a consequence of the tissue viability service team being small and short-staffed. It did not have the capacity to conduct visits to review patients in every case where concerns were raised and/or deterioration was evident. A related area in this respect is the reliance on outmoded or cumbersome referral processes, such as the need to

complete a lengthy form to request access to the tissue viability service. There do not seem to be IT systems or processes in place that could facilitate and aid timely referral to specialist advice, such as telemedicine systems.

The inconsistent photographing of wounds (a key aid to monitoring progress or deterioration) may have been due, in cases that happened after the outbreak of iGAS was known about, to the requirement that ICT nurses stop taking their camera phones with them when visiting patients, as part of the infection prevention and control measures implemented. It has not been possible to establish exactly when that restriction came into effect, but a number of sources told the review team that this was a factor in some cases.

A similar restriction was put in place, again at a date after the outbreak that it has not been possible to establish exactly, on the use of basic observation equipment such as blood pressure and heart monitoring equipment, and Doppler (ultrasound) scanners. Because the ICT nurses were unable to use such equipment, and no other alternatives seem to have been available, their capacity for monitoring and assessing the condition of their patients was reduced.

Despite these possibly mitigating factors on monitoring progress and deterioration, the review team were told that the routine taking and recording of basic patient observations, such as temperature, blood pressure and other visible physical signs, was not regular practice in the care given in the community (see example 2 above: 'baseline observations were not recorded').

Example 5

There are no records of physiological observations being recorded during the month, and no photographs were taken to monitor progress or deterioration in [person Q's] wounds…

Another way of determining the possible presence of infection is the taking of wound swab samples. With the benefit of hindsight it is possible to identify

occasions in some of the cases when the swabbing of wounds might have led to the earlier accurate identification of the infecting bacteria, which would have guided effective antibiotic treatment. In mitigation, Provide CIC local guidelines for their ICT nursing teams on leg ulcer management state that *routine bacteriological swabbing is unnecessary unless there is evidence of clinical infection…* The Provide wound management guidelines state, with regard to clinical investigations: *All chronic wounds contain bacteria, but not all are infected or should be routinely swabbed for Microscopy [sic], culture and sensitivity…Identifying wound infection should be viewed as a clinical skill, which can be supported by laboratory findings when necessary…*

It is therefore possible that in the clinical judgement of the healthcare professionals providing care to these individuals, it was not necessary to swab the wound(s). Nevertheless, in some of these cases there was cellulitis or systemic infection present. Provide wound management guidelines state: *Patients with wounds that show spreading cellulitis and/or systemic infection should have a wound swab and cultures taken to identify the offending organism, and to assess for a differential diagnosis.* Furthermore, in some cases it would appear that where infection might have been present, swabs were not taken.

> **Example 6**
>
> [This person had been identified from an earlier swab as infected with GAS] *[Person F's] GP also requested that [F's] wound be re-swabbed when the dressing was next changed… The ICT visited [them] on five more occasions during this period to dress the wound… Over this time [F] was very concerned that the requested re-swab had still not been taken. The ICT visited F…and [their] leg was recorded as red and hot. The swab was taken nine days after it was first requested…The ensuing nine-day wait…may have delayed the detection of the on-going infection with GAS leading to the subsequent invasive Group A Streptococcus (iGAS) infection.*

Example 7

[Person P's] leg wounds were not swabbed to identify the source of infection, either by the GP or ICT, although antibiotics for a serious bacterial infection were prescribed. This may therefore have been a missed opportunity to identify the source of infection.

Example 8

Although there was redness and discharge in [person G's] leg ulcer, G did not feel ill, and so might not have fully met the criteria in the local guidance for wound swabbing. However, as G had a history of ulcerated legs, and had been on several courses of antibiotics, it is the opinion of the clinical advisers to this review that it might have been appropriate to have swabbed the wound at this point.

It is important that policies and guidelines on wound and ulcer management are up to date and clearly written. The review team found that the Provide leg ulcer management guidelines had an expiry date of March 2019. The review team's clinical advisers in these areas assessed the guidelines as at times unclear or ambiguous in expression, for example in the advice on when to take wound swabs. These guidelines are a key resource for staff to support their clinical practice.

In April 2019 Public Health England issued the following guidance in a note for GPs and Provide nursing teams in the infection outbreak area: *[PHE] have therefore recommended that district nurses take swabs from all those they see with wounds of any kind in the next couple of weeks…* The CCG also at this time issued a community infection incident briefing note confirming this advice as part of their control measures: *[we are suggesting that:] Patients with wounds are swabbed as a matter of urgency and any with GAS are treated promptly with a course of antibiotics before they develop iGAS or pass infection on to others.* Of the nine individuals who were being treated after April, however, in only one case do the records indicate that a swab of an open wound was taken, in accordance with these directives.

Example 9

[Person Q's] left arm was swabbed on 15 April (as part of the monitoring of the iGAS outbreak) by an ICT nurse.

Although in this last example the directive to swab a wound was followed, the results confirming growth of Group A Streptococcus (GAS) did not reach Q's GP because of a confusion following Q's change of GP practices. This meant that Q did not receive timely and appropriate treatment – in this case for two weeks. By that time Q was very ill, was admitted to hospital, and died just under two days later.

5.2 Wound management practitioners/training/competency

Provide's Wound Management Clinical Practice Guidelines v2 2018 state that *those who undertake assessment, planning, implementation and evaluation of care should be trained/educated/competent in wound management*. This document also requires that *All Provide health care professionals involved in the care of patients with chronic wounds should attend the 'In House' or online courses, unless they have attended another external recognised wound management course within the last three years and maintained their knowledge and skills.*

Provide's Leg Ulcer Management Guidelines v4 (expired March 2019) specify that *A healthcare Assistant/Associate Practitioner trained to a minimum of NVQ level 3, who has achieved competency by successfully completing a local leg ulcer management training course may provide care following assessment by a registered nurse and formulation of a care plan.* ***Health Care Assistants may only practice*** *[sic]* ***leg ulcer management in a supervised clinical environment …***

There were a number of cases in the review process where wound care was undertaken by healthcare assistants (HCAs; also known as support workers - HCSWs). This included changing specialist dressings and bandages, for which skilled clinical judgement is needed, both in selecting appropriate dressings for the types and conditions of wound, and applying them correctly. As noted above, Provide's

clinical guidelines in these areas require that such care should be carried out only by trained staff, or by HCSWs working in a supervised clinical environment. It has not been possible to establish during the review process how or whether such conditions for HCSWs carrying out these procedures were met, or whether they had the requisite training. For example:

- On two occasions in October Healthcare Support Workers (HCSWs) undertook wound dressings unsupervised.

- HCSWs were changing dressings. In meetings with the review team, they said that they followed the Mid-Essex wound care formulary for dressings. They understood the process of when to escalate to senior or specialist staff if they felt a wound was deteriorating or becoming infected, but there is no record of such escalation taking place in this person's case.

- Various kinds of dressings and bandages were applied throughout January and February 2019 by HCSWs; again no escalation or basic observations, for example recording of wound sizes or photographing the wounds, took place.

- Wounds were being dressed by a number of qualified and unqualified staff throughout D's care…

Reviewers were told that wound care and pressure ulcer training for all ICT registered nursing staff is mandatory, but did not always take place because of capacity.

There were two cases in which examples were cited of an individual's dressings being changed by family members. On one of these occasions the records indicate that the ICT nurse visit was cancelled by the relative because they had changed the dressing themselves; the ICT told them not to do this in future, but to call the nursing team and they would do it.

5.3 Wound management in hospital

MEHT's 'Leg Ulcers Pathway- 2018' document requires that a patient's compression bandages should be removed (with the patient's consent) in the emergency department (ED) within six hours of admission to carry out early skin assessment and determine a care plan.

Example 10

There was no care given to [person E's] legs, despite notes indicating that [their] leg was 'red and warm to touch' … yet there is no written description, photograph or formal assessment in the records… [this] could have led to consideration of infection in E's wounds.

Example 11

On admission to [hospital] [person Y] was placed on the sepsis pathway, but [their] leg wounds were not examined…although Y's infection was noted on Y's clinical records, the dressings were not taken off for a physical examination. This was not in accordance with the existing guidance.

The review team were told that emergency department staff did not remove compression bandages, as they did not have replacement dressings or bandages in stock, or the appropriately trained staff to undertake the task. Wounds were not routinely examined if already dressed. The consequence of not being able to remove these types of bandages to enable examination or the taking of a swab could result in delay in giving appropriate treatment.

It is good practice that on admission all patients who are suspected of having sepsis, and have leg ulcers or cellulitic legs, should have dressings (including compression bandages) removed and, where appropriate, a swab taken for culture and sensitivity testing. NICE guidance on the recognition, diagnosis and early management of sepsis recommends that a thorough clinical examination should be undertaken to look for sources of infection. Any person with a breach of skin integrity is a risk factor for

sepsis (NICE guideline [NG51], section 1.1 – 1.2, 'Identifying people with suspected sepsis', July 2016, updated September 2017).

Example 12

…there was no referral [of person Y's condition] to [the hospital] tissue viability team. [The review team were told] that the hospital tissue viability team did not have the capacity to routinely examine leg wounds, and focused assessment on pressure ulcers.

These and other examples across some of the reviews indicate that specialist advice or information was difficult to access both in the community and in MEHT, partly because of caseloads and lack of capacity in the specialist areas. Specialist advice when given tended to be communicated remotely, rather than on visual examination.

Findings

Wound management in both the community and in hospital was not always in line with standard practice, or did not follow the local guidelines. On many occasions there was inconsistency in clinical practice in undertaking the necessary assessments and monitoring process. Findings from Provide's Wound Assessment Clinical Audit Report 2019/20 on the three integrated nursing care teams demonstrated that the wound assessment templates on SystmOne were not being completed consistently to systematically document and monitor progress or deterioration of wounds. This indicates that guidelines were not being fully complied with by these teams.

Wound swabs were not taken on a number of occasions, or were delayed, even when there was indication of infection; the local guidelines seem to deter the clinician from bacterial swabbing. Even after the PHE recommendations in April that all wounds be swabbed, the records of the cases in the period after April

indicate that these directives were followed in only one case. These factors, along with the limited access to specialist support, made it difficult to identify deteriorating wounds and take timely preventive or remedial action.

Provide CIC may wish to consider whether its community HCSWs are required to deliver care beyond their competence, and if HCSWs are being asked to support registered nursing staff with wound care, that appropriate processes are in place for their training, and for the supervision and assessment of their practice. Local guidelines on this would also need to be updated to reflect any such undertaking.

In hospital, wounds were not always examined, reviewed or considered as a source of potential infection. It should be standard practice to review wounds when a patient presents with signs of possible systemic infection. This is especially important when they are elderly, frail, with serious underlying medical conditions, and therefore in the category of high risk of infection.

Clinical policies and guidelines are in place to support staff in their clinical decision-making and practice, and should be unambiguous and readily applicable. It is acknowledged that giving guidance on the making of clinical decisions must always take into account the experience, skill and judgement of the clinician, but it is pertinent that the majority of the thirteen cases in which people died, having contracted iGAS, occurred after the outbreak was known about.

Systems should be in place to ensure that guidelines are appropriately applied and followed and any deviations from the guidelines should be challenged to ensure standard practice is being followed. If specialist advice is required there should be easy and timely access to these services to support clinical practice.

5.4 Identifying clinical deterioration

- **Community**

Community nursing services (such as those delivered by Provide CIC and EPUT) represent a lifeline for many people and play a key role in helping them to maintain their independence, manage long-term conditions, and treat acute illness. The King's Fund 2016 research (Understanding quality in district nursing services) found that *At their best, they [district nursing teams] deliver an ideal model of person-centred, preventive and co-ordinated care, which can reduce hospital admissions and help people to stay in their own homes*.

Among the thirteen iGAS outbreak cases that were reviewed, there were several in which individuals became increasingly unwell over a period of time in the community, yet their deterioration either went unnoticed, or was not acted upon promptly. Sometimes their condition had become so serious that they were very ill before acute medical intervention was sought.

As noted above, basic observations or holistic assessments were not always routinely taken or recorded as a means of detecting progress or deterioration, and escalation to expert/specialist clinical advice was not always sought when the person's condition worsened.

Example 13

Given [person J's] history of recurring pressure ulcers, some of which became serious, there seems to have been no escalation of J's condition, for example to J's GP or the tissue viability team…The review team were informed that it is not standard practice for ICT nurses routinely to monitor and record observations (such as temperature and pulse).

J's records indicate that [they] were underweight, yet there is no record during this period [one month] that a standard nutritional assessment tool (MUST) was used and its findings noted and acted upon [for example, referral to a dietician].

Example 14

[The reviewer was told by person M's close family member that they] noticed deterioration in M a few days after M's admission to the home for respite care; M 'didn't appear to be drinking and was very pale and confused.' [This relative] was disappointed [they] had to prompt staff to call a doctor to review M…

The [nursing home's] falls observation record shows hourly annotations, but with three gaps in the early hours when no observations were recorded…Medical advice (GP out of hours/emergency ambulance) should have been sought at the time of M's fall [because of their pain, and circumstances of the fall]…as a minimum, clinical observations should have been made at least hourly and the patient disturbed from sleep, given the potential for serious injury and life-threatening consequences.
[M's relative told the home's staff of their concern that M had slept through the night – something they had not done for fifteen years]. Knowing this should have been a 'red flag' to staff, even without clinical observations.

Example 15

There are no records of physiological observations being recorded during the month…[person Q] said [their] legs were stinging, and [their] behaviour was described as increasingly challenging; all of these could have been indicators of possible infection

Recognising the 'softer signs' that a person may be deteriorating requires that they are well known to the healthcare worker, and that they are alert to possibly subtle changes in the person. These could include indications of increased pain, their not eating and drinking, being unusually sleepy, their colour changing, their breathing more heavily, and possibly feeling hot when touched – all signs that can be identified without the need for equipment.

Example 16

Whilst the care home records report that [person Z] was feeling 'sore' the following morning, the district nurse's holistic assessment does not mention that Z was in pain as a result of the fall.

In the following example, a healthcare support worker was alert to a change in the individual's demeanour and presentation, and sought advice from the GP appropriately; it therefore illustrates the kind of holistic, person-centred assessment, observation and action that represents good practice, as noted above.

Example 17
[Person G] was diabetic [type 2], and on an ICT visit was found to be *clammy in the face and sleepy. As G was diabetic, the healthcare support worker [HCSW] spoke with a doctor at the GP practice to seek advice about managing G's blood sugars.*

When a high number of healthcare professionals are involved in an individual's care, identifying signs of potential deterioration becomes more difficult. In one case, approximately thirty-two different healthcare workers provided care to an individual over a three-month period. In another, there were nine healthcare professionals involved in the person's final month of care, including two GP visits, attendance by community nurses, healthcare support workers and agency staff. It has not always been possible in every case to determine how frequently any one healthcare professional (re)visited an individual, or if they attended alone or accompanied by another team member.

The review team were told that the ICT caseload of patients was heavy, and there were staff shortages. When a number of staff are involved in the [wound] care of one individual, the opportunities for consistency in care and monitoring will be limited. This pressure on the nursing teams would have been intensified when infection prevention control measures introduced from April following guidance from Public Health England, as a means of reducing risk of cross infection, required each district's team not to cover the other teams' areas. This meant that each team

was more than usually stretched to cover its own caseload, without the help of the other teams. As a consequence of these and other infection control measures (for example the restriction on use of equipment following awareness of the outbreak), the quality of care may have been compromised, resulting in an increasingly task-focused approach, and visits being postponed, to the detriment of continuity of care.

Care home staff and healthcare professionals in the community did not always show alertness or sensitivity to the 'red flags' (noted above) in the demeanour or behaviour of individuals for whom they were caring. A residential home without qualified nursing staff employed should have a low threshold for seeking early clinical help.

> **Example 18**
> *On 28 April [person Q] seemed unwell and uncommunicative and wanted to spend more time in bed…It was agreed that staff would contact [Q's] GP if [they] worsened overnight. The following morning Q was found unwell in bed…The GP arrived in the morning and as a consequence of Q's observations (temperature, and oxygen saturation levels) and [their] confused state, diagnosed sepsis.*

Care home records indicate that Q had not been settled for a number of days, was not eating, and was challenging to staff. Q was a new resident in the care home, and because there was no transfer of their care plan from one ICT to another, they did not receive any community care or treatment for their wounds for two weeks. Signs that Q was unwell and behaving erratically during this period in the care home were not acted upon in a timely way.

The review team were told that Provide community nursing team do not use the National Early Warning Score (NEWS, introduced in 2012, updated December 2017 as NEWS2), which is a system for standardising the assessment and response to acute illness, and individual observations are not routinely undertaken or recorded.

Adopting such tools and methods would assist in providing a more detailed and holistic, person-centred assessment of the individual.

The EPUT nursing team are using the earlier version of NEWS, and this was effectively implemented in the one case of the thirteen reviewed where the individual was cared for by this team.

- **Hospital care**

Mid Essex Hospital Trust (MEHT)'s Adult Patient Observation Policy (July 2018, updated May 2019) provides guidance to medical and nursing staff on the undertaking and recording of observations. This policy states that it is the responsibility of the registered nurse and medical staff to ensure *timely interpretation of the observations and the consequence of decisions made*. One of the tools the hospital uses to support this requirement is the National Early Warning Score 2 (NEWS2) to enhance patient safety, and once the NEWS2 'trigger process' is activated it is the responsibility of the medical and registered nursing staff to ensure compliance with the escalation process.

Example 19

There is no record of observations being taken between [person G's arrival at ED at 17:20 and 20:58. Then the observations were recorded four-hourly [as indicated by G's NEWS]. Observations continued until 11.43 [the following day]. This was the last time any recordings appear to have been taken. These observations demonstrated a falling pulse, whilst G's temperature was getting higher.

Not only was there an observations gap of nearly four hours when G was in the ED, there was also a further gap of nearly ten hours when no observations were recorded at a time when four-hourly observations were part of G's care plan and their deterioration was evident.

Example 20

Throughout the day [person P's] observations were taken: [their] blood pressure was consistently low, and [they] had a fluctuating NEW score …

At 12 noon the occupational therapist reported that P was drowsy and unable to maintain oxygen saturation, and P's administration of oxygen was further increased. [The therapist] informed the ward staff of this development.

During P's time in hospital there were occasions when the deterioration in their clinical presentation should have been escalated to more senior clinicians. P was not on an end of life pathway and was not expected to die. These may have been missed opportunities for urgent medical review.

MEHT's Early Identification and Treatment of Sepsis document requires that: *Triage Nurses in the Emergency Village use the sepsis screening tool on all patients that have: 1) a single NEWS of 3 in one parameter; 2) an aggregated NEWS of 5 or more; 3) clinical concern of sepsis…* In the thirteen cases reviewed there are examples where sepsis was promptly considered and identified by paramedics and ED clinicians, and policy was appropriately used and implemented. There are, however, a few cases where there was a delay in the implementation of the sepsis screening and action tool, or sepsis was not considered. In some of these cases this may well have been because other serious primary conditions were being prioritised; nevertheless infection was clearly on the minds of medical staff because IV antibiotics were administered, or blood cultures taken.

Example 21

[Person D] was very ill when [they] arrived at Broomfield Hospital, and in spite of focused treatment to identify and treat [their] infection, D did not improve. The sepsis screening and action tool was implemented, D was regularly reviewed, and [their] overall care reflected good practice.

Example 22

[When [person G] was admitted to the ED, the sepsis six pathway was initiated; two of the required actions involve giving of intravenous (IV) fluids and (hourly) monitoring of urine output]. *Four litres of intravenous fluid were prescribed after 18:10, the second at 22:50, then there was a delay with no further infusions recorded as given until 17:30 on [the following day]. There is no record that G's fluid intake and output was monitored hourly, as stipulated in the local guidelines. This apparent omission is important as such monitoring is a means of assessing kidney function, because G would have been at risk of kidney failure.*

Example 23

On admission to the ED, [person M's] NEWS was recorded as 6. *The sepsis pathway form was not completed, as would be expected with a NEWS of 5 or more.* However, the treatment given to M indicates that clinicians had a high suspicion of sepsis.

Example 24

[Person F] had a NEWS of 10…as assessed by the ambulance crew, and arrived in the emergency department with a pre-alert for sepsis, but no record of starting the sepsis 6 pathway was made. However, it is clear that medical staff suspected sepsis, as F was prescribed IV antibiotics.

Example 25

*The sepsis screening and action tool was completed [for person T], and the plan was commenced in line with guidance…*T was admitted at 09:56, antibiotics were prescribed promptly at 10:50, but they were not administered until 12:00, outside the sixty minute period from admission recommended in local guidelines.

MEHT's document Early Identification and Treatment of Sepsis states (6.2.2): *Nursing staff are responsible for drawing up the antibiotics and giving them within 10 minutes of them being prescribed.*

Findings

It is the responsibility of all healthcare professionals to follow their own codes of conduct and guidelines. The NEWS (national early warning score) tool is a guide used by clinical staff to quickly determine the degree of illness of a patient. Good practice is that it should be used to support and enhance clinical judgement of a patient's condition.

The Nursing and Midwifery Council code, section 13: 'Recognise and work within the limits of your competence' states: (13.1) *To achieve this, you must, as appropriate: accurately identify, observe and assess signs of normal or worsening physical and mental health in the person receiving care; (13.2) make a timely referral to another practitioner when any action, care or treatment is required.*

If NEWS2 had been in use in the mid Essex community, it is possible that deterioration in the condition of those individuals who later contracted the iGAS infection might have been detected or recognised and acted upon sooner. Use of such a diagnostic tool would have given the systematic and authoritative basis on which healthcare workers, for example, might have felt more assurance in escalating to expert advice, or to call for medical help from GPs, out of hours or the ambulance service before the person's condition became so severe they were almost beyond help. ICT nursing teams might also have reacted in a more timely way to the deterioration of their patients by using such a tool.

In Broomfield Hospital, even though there were examples of good and timely practice in the use of NEWS2 and the sepsis six tools, there were also cases where they were not consistently or thoroughly implemented or followed through. By identifying the early signs of a patient's deterioration, staff have the opportunity to intervene, and implement an appropriate care plan, or escalate for urgent clinical review.

Although there is a connection between continuity of care and the recognition of clinical deterioration in a person's condition, this is not an exclusive relationship, and care provided by many different staff to one individual can still be safe. Nevertheless, the quality of a person's care in the community improves if that person is regularly seeing the same nurse, or a relatively small team of nurses. This enables continuity of care, the benefits of which include the smaller number of staff being able to monitor progress and establish the effectiveness of treatment, detecting improvements or deterioration in a person's condition. It will also enhance the development of the relationship between the person being cared for and the nurse(s); trust and confidence can be established and built upon, and this will reflect in the quality of care the nursing team is able to deliver (The King's Fund, 'Understanding Quality in District Nursing Services', August 2016). Provide CIC should consider how it assures itself that continuity of care is enabled through its structuring of team sizes and deployment to maximise high quality care, as this may have been a factor in the apparent lack of early recognition of the deterioration in the clinical condition of some individuals being cared for.

5.5 Antibiotic therapy

The usual therapy for treating GAS and iGAS bacterial infections would include using penicillin-based antibiotics. There are three key factors in making judgements about the choice of antibiotics:

- Clinical judgement
- Efficacy
- Formulary

There are local formularies for both primary and acute services to provide guidance on choosing and prescribing antibiotics, oral and/or intravenous. In the thirteen cases reviewed, seven individuals were identified at various stages in their clinical records as being 'allergic' to penicillin. If a person with a true penicillin allergy is given penicillin, the immediate consequences can be very serious, with reactions such as anaphylactic shock, swelling to the face or neck which may cause breathing

difficulties, or a rash/hives. Intolerance to penicillin usually causes less serious reactions, such as diarrhoea or a minor rash. A history of a penicillin allergy/intolerance is not uncommon – one in fifteen of the population have some degree of adverse reaction to penicillin-based antibiotics. In most cases this will be mild to moderate (www.nhs.uk).

Of the seven individuals in the iGAS outbreak whose care was reviewed and who were identified as penicillin-allergic, five were given penicillin-based antibiotics at some point in their care.

Example 26

The GP visited [person F] at [their] home … and changed the antibiotics to clarithromycin because of [their] intolerance to flucloxacillin [a penicillin-based antibiotic] (which presented as an upset tummy). There appears to be a misleading entry on the GP surgery clinical record system (SystmOne), which indicates that F was allergic to flucloxacillin; it might have been more accurate to record that F was intolerant to it, and also to erythromycin.

…The ambulance and ED admission records indicated that F had no known allergies. When F arrived in the ED, F was administered flucloxacillin, to which F was intolerant. When it was later noticed that F's records indicated a penicillin allergy, [their] antibiotics were changed.

After being prescribed flucloxacillin in the ED, F's clinical records indicate that there were *no signs of allergic reaction noted.*

Example 27

The administration of intravenous (IV) penicillin-based antibiotics (co-amoxiclav) started in ED … [person Y] was allergic to penicillin, which was noted on the ambulance record … Y's antibiotics were changed to IV levofloxacin, in the context of [their] penicillin allergy.

The clinical records do not identify whether Y had any adverse reaction to the IV co-amoxiclav.

Example 28

Clinical signs of infection were noted at the initial assessment … and erythromycin was prescribed … [Person A] had a known intolerance to penicillin, the antibiotic that would be the first choice when not contraindicated… Doxycycline was prescribed, as this was listed on the [microbiology] report as an appropriate antibiotic.

Erythromycin and doxycycline administered for bacterial infections were appropriate alternatives and safe for an individual with a known penicillin allergy. However, person A was later prescribed phenomethylpenicillin following discharge from hospital. The review was not able to establish *from the GP surgery why this was prescribed for a person with penicillin intolerance.* The GP clinical record system does not indicate whether A had an adverse reaction or not.

Example 29

The GP was told of [person D's] intolerance to some antibiotics by the care home staff and they prescribed trimethoprim as a first line antibiotic for a chest infection. [This is an appropriate antibiotic for an individual intolerant to penicillin.]

[D was later prescribed doxycycline by their GP, an alternative to a penicillin-based antibiotic]; *[This GP] told the reviewers that they were unaware that D was 'sensitive' to this antibiotic; this was not recorded on the GP practice record system (SystmOne)*. In both these situations it appears that the records do not hold entirely accurate information on the individual. On this occasion the GP was being informed by the care home staff.

Example 30

As [person G] was recorded to be allergic to penicillin, G's GP prescribed clarithromycin, an antibiotic used to treat skin infections for patients intolerant or allergic to penicillin.

…As G was recorded as being allergic to penicillin, discussion was held between [the] GP…[and the] ICT Infection Prevention Doctor, and an alternative antibiotic (cephalexin) was prescribed.

…Although G was recorded as allergic to penicillin, a review of [their] case notes showed that in [date] G was prescribed a penicillin-based antibiotic with minimal side effects (diarrhoea). This recording of a penicillin allergy rather than an intolerance meant that G was again prescribed clarithromycin, which is the second line choice, rather than a penicillin-based antibiotic, which is known to be the antibiotic of choice for certain infections.

…Even though G's notes indicated – perhaps inaccurately - that G was allergic to penicillin, G was given IV penicillin-based antibiotics on arrival at hospital… the antibiotics were changed when the note to this supposed allergy was identified…

It was unclear whether G was allergic or intolerant to penicillin, but clinical records indicated that G had an allergy. Penicillin-based IV (intravenous) antibiotics were nevertheless administered while G was in hospital. When the error was noted and a suitable alternative antibiotic prescribed, there was confusion whether to administer the antibiotics orally or intravenously, and whether G was being treated for cellulitis or sepsis.

Findings

All drugs have the potential to cause side effects, also known as 'adverse drug reactions', but not all of these are allergic in nature. Other reactions are idiosyncratic, pseudo-allergic or caused by drug intolerance…About half a million people admitted to NHS hospitals each year have a diagnostic 'label' of drug

allergy, with the most common being penicillin allergy. About 10% of the general population claim to have a penicillin allergy: this is often due to a skin rash that occurred during a course of penicillin in childhood. Fewer than 10% of people who think they are allergic to penicillin are truly allergic… However, use of these antibiotics in people with an insubstantial label of penicillin allergy may lead to antibiotic resistance and, in some cases, sub-optimal therapy. (NICE: Drug allergy: diagnosis and management, Sept 2014, clinical guideline (CG183)).

In only one of the cases cited above where an individual labelled as allergic and administered penicillin in the community was any adverse reaction subsequently recorded (severe diarrhoea), and this cannot be confirmed as an adverse reaction to the penicillin.

Of the three individuals labelled as allergic and given penicillin in hospital, in only one case was a note made in their clinical records whether or not there was an adverse reaction to it (in this case, there was not). There seems to be inconsistency or inaccuracy in the ways these individuals' penicillin 'allergy' is recorded in their notes, with no clear distinction made between intolerance and a 'true' drug allergy. This could lead to a false label of a penicillin or other allergy, particularly if the person's reaction took place many years previously and details about their reaction have been lost.

The prescribing of a penicillin-based antibiotic to an individual with a known/recorded allergy is a drug error and should be recorded as a patient safety incident on the incident reporting system of the healthcare provider. In only one of the cases identified above did this occur.

Not only were some individuals prescribed penicillin when their records indicated an allergy to it, there were also instances where the noted allergy was either overlooked or did not follow them as they passed from care in the community to another provider (the ambulance service or acute hospital). There were occasions,

for example, when an individual arrived at the ED with 'no known allergy to drugs' recorded in their ambulance records, when their allergy was recorded in other clinical records. On another occasion the ambulance service noted a penicillin allergy in an individual, but this was not apparently picked up immediately in the ED.

As noted above, local and national formularies support clinicians' judgement in choosing and prescribing antibiotics for bacterial infections like GAS and iGAS. Choice of antibiotics would also therefore take into account a person's medical history, including previous antibiotic treatment, and any adverse reactions. In the minutes of a December 2019 meeting of the Mid Essex CCG Health Protection and Epidemiology Group there was retrospective discussion of the efficacy of the penicillin-based antibiotic flucloxacillin that was prescribed in a number of early cases (at least three of the thirteen cases reviewed by Facere Melius were among those who were given this antibiotic at some point in their treatment, including at least one who had been labelled as 'allergic' to penicillin). During the course of the review of the thirteen cases of individuals who died, there was some confusion apparent about the efficacy of some of the alternative non-penicillin antibiotics that were administered for the treatment of GAS and iGAS to those individuals who had been labelled as allergic to penicillin; these included clindamycin and clarithromycin.

5.6 Infection prevention and control

In order to meet the Care Quality Commission (CQC)'s registration and regulation requirements, all healthcare providers must be able to demonstrate compliance with regulation 12(2)(h): *assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are healthcare associated* (CQC 2015). By following the Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance 2018, providers will be able to show how they meet this regulation. The Code states (p.5):

Good infection prevention (including cleanliness) is essential to ensure that people who use health and social care services receive safe and effective care. Effective prevention and control of infection must be part of everyday practice and be applied consistently by everyone.

Good management and organisational processes are crucial to make sure that high standards of infection prevention (including cleanliness) are developed and maintained.

As a response to the cluster of cases arising in Mid Essex involving an unusual strain of Group A Streptococcus – emm44 - raising concerns of a potential outbreak, Public Health England (PHE) established an iGAS Cluster incident management team (IMT). In its first three meetings (12 March – 5 April) a range of infection prevention and control measures in the community were initiated. These included screening nursing staff for infection by swabbing, and later offering preventative antibiotics; removing higher risk clinical items to suitable cupboards; providing nurses with hard cases for the transportation of equipment, and reviewing the cleaning schedule and frequency at the ICT base.

The IMT meeting minutes (for example 26 March 2019) indicate that nurses on the ICT team had been given instructions on keeping their own bags clean and changing and laundering uniforms. The use of a shared Doppler (ultrasound) machine was discussed – each of the three teams in Mid Essex had one. There was also discussion of the procedure for nurses to procure dressings, and of the use of personal protection equipment (PPE). Each member of the team was supplied with disposable gloves and aprons, which were to be worn when treating every patient. Surgical masks were not required to be worn, although it was acknowledged that some advice stipulated the need to wear them, or all-round overalls. The three teams were to be given training on infection control.

On 5 April the PHE consultant in communicable disease control wrote to all GPs in the outbreak affected areas (Braintree, Chelmsford and Maldon) recommending that *district nurses take swabs from all those they see with wounds of any kind in the next*

couple of weeks. Should we find any further cases, the nurse will be contacting you to prescribe some antibiotics…

Only one example of bacterial wound swabbing taking place in accordance with this recommendation was found in the nine cases of individuals who were still being treated in the community after 5 April.

The findings below concerning infection prevention and control measures taken in the community in response to the outbreak, and their effectiveness, only relate to the thirteen cases reviewed. There may well be other factors that would have been pertinent in the cases of people who contracted the infection, but who survived; these lie outside the revised scope of this investigation.

In only one of the reviewed cases (apart from the one person whose wound was swabbed) was a record mentioned of the infection prevention and control measures in the community as required by the IMT from March onwards.

> **Example 31**
> *[January 2019] It is not possible to ascertain from the records whether other appropriate infection control measures were taken, such as each dressing being carried out using separate bowls and bowl liners… Photographs used to evidence the condition of [person G's] wound also show examples of dressings, etc. lying on the floor…not on a sterile surface.*
>
> *[In early March] G declined the use of bowl linings to wash [their] legs and requested that the same towel be used for both legs. The nurse explained the risk of cross infection…*

Although this example falls before or very soon after the IMT measures were introduced, it shows how it was not possible in the thirteen review cases to demonstrate authoritatively how rigorous was the compliance in the community with existing local guidelines on wound management and infection control.

Example 32

One individual (A) who lived in a care home was being treated by the ICT; they were also treating another resident in the home, who had been diagnosed with Group A Streptococcus, and was known to be MRSA positive. The home did not have important information about this other person's infection status. These two residents shared the same communal areas, and lived on the same floor. There were four occasions in one four-week period when the ICT staff member treated A directly after treating the other resident for wound care. Standard infection prevention and control precautions when administering wound care should stop the spread of an infection from one resident to another. Nevertheless, as noted in the minutes of the first IMT meeting on 12 March, 2019: *In the past human carriers were considered the likely source of outbreaks but more recently it has been recognised that contamination of equipment and the environment (carpets, curtains and even shower heads) may also be an issue.* There would appear to be a possibility, in this person's case, that cross infection might have taken place.

The Facere Melius senior oversight team made a late request to Provide and MEHT for minutes of their infection prevention group meetings held during and after the outbreak, in order to review what actions were being taken at that time. Information subsequently received from Provide CIC demonstrates that the outbreak and associated risks were being discussed through its governance system. MEHT did not respond to this request for information.

The review team who looked into the thirteen iGAS cases were told by various representatives of Provide that after the iGAS outbreak was known about they were given confusing and sometimes conflicting messages about infection prevention and control measures. This may have been a consequence of the evolving nature of the

situation at the time, when a complete picture of the outbreak, or appropriate and effective infection prevention and control measures, was not available. The review team were also told that the focus of these measures seemed to relate to the community nursing teams, but that there were other people visiting or involved with the care of the elderly and frail people they were treating, from domiciliary, care home and social care staff and GPs, to relatives of the people being cared for; none of these appeared to be required to adhere to the same control measures as the Provide staff, or to be informed about them. Public Health England and Mid Essex CCG might have considered taking steps to assure themselves that any advice that they sent out specific to any one of these groups had been consistently communicated to, and understood by, all the other groups involved in caring for individuals in the community.

The review team were told that some community nursing staff were informed in approximately May or June 2019 that there was a confirmed outbreak of iGAS. Provide senior managers were informed by Public Health England (PHE) of an outbreak of iGAS in mid-February 2019. In mid-March a screening programme of Provide clinical staff was initiated in the Braintree locality. There is therefore a confusing picture of communication timelines indicating when front-line staff in the community were informed or became aware of GAS and/or iGAS, and of additional infection prevention and control measures that were required. Staff mentioned basic hygiene such as hand washing and wearing gloves, but seemed less certain about PPE and some of the other measures in the community required by the incident management team.

Provide staff told the review team that stocks of equipment were removed from staff cars, nurses were instructed not to take camera phones into clients' houses on visits, and basic observation equipment such as blood pressure monitors were no longer permitted. Equipment would only be available from one area, where a specific storeroom was established for staff from which to collect dressings, equipment and supplies. This was shared by all staff, who would collect dressings, creams and equipment, with no thorough infection prevention control apparently in

place for this central area. Used equipment would than have to be returned after each visit and decontaminated for subsequent use.

A Public Health England team undertook a site visit to Provide district nursing service on 25 July 2019 to review their infection prevention and control (IPC) arrangements, equipment use, decontamination, and operational procedures (Draft Report, undated). Based on what they witnessed during this visit, the team found that although infection control practice at that time appeared satisfactory, there were a number of areas that required improvement. This site visit took place towards the end of the iGAS outbreak, and after the last of the thirteen individuals reviewed had died, and therefore the report might not have picked up on any lapses in infection control practice that could have contributed to the significant number of earlier cases.

The PHE team's findings arising from their visit to Provide district nursing service included the need for a review of infection control policies, and the development of a community outbreak plan. From their discussions with staff that day they identified a lack of clarity in IPC training. The PHE team recommended that future training needed to be relevant and tailored to the duties and procedures of staff, and the requirements of community nursing and environments. This would include when, where and how to use personal protection equipment (PPE) and its safe disposal, and training in the basic principles of IPC. Staff would benefit from understanding the rationale as to why they needed to abide by IPC practice and procedures so that these are embedded in their day-to-day clinical practice, and not seen as an add-on to their duties.

The PHE team also identified that communication to and between staff, patients and relatives appeared confused; for example, clear messages were needed about who should wear PPE, why it was required, and for what procedures. Better communication with other agencies dealing with patients in the at-risk groups was needed, to ensure a consistent and effective approach to infection prevention and control.

This confusion or lack of clarity might be attributed to the lack of national guidance for iGAS outbreaks in the community; in acute and maternity services there is such guidance. This situation is compounded by the gap in specialist knowledge and experience in the infection prevention and control workforce, nationally and locally. Provide CIC has itself identified the lack of local IPC team capacity as a risk.

On 29 May 2019 the leadership of the (iGAS cluster) incident management team transferred to Mid Essex CCG. The Mid Essex CCG communications plan indicates that the Broomfield communications team sent an internal email to all staff on 7 June asking them to be vigilant for iGAS in all patients attending with wounds. On 3 July the MEHT group medical officer sent a further communication to all staff about the iGAS outbreak, reinforcing the need for awareness and vigilance.

MEHT's 'Standard operating procedure for Group A Streptococcus (GAS) and, Invasive group A Streptococcus (iGAS) in a healthcare setting' (no date, but due for review October 2019) states: *patients with a suspected or confirmed infection should be isolated in a single room with en suite facilities.* The MEHT's 'Patient Isolation Policy' (version 4, 12 February 2018), section 5.2, states: *Patients who are known or suspected to have an infectious disease or who are carrying a multi-resistant organism will also require isolation. This will usually mean caring for the patient in a single side room with precautions being taken to contain infection within the room.* Section 5.4 states: *A decision to isolate a patient may be made by nursing or medical staff and/or on the advice of the Consultant Microbiologist or IPT [infection prevention team].*

Example 33

[In Broomfield Hospital] Microbiology results…confirmed that [person D] had Group A streptococcus (GAS) infection. [There was a visit from the Infection Prevention Team two days after this confirmation; personal protection equipment was to be used, strict hygiene maintained and equipment

cleaned. There was no indication in the records that D was isolated. They died five days after the GAS infection was confirmed.]

Example 34

…the hospital microbiologist called the ward to report that Group A Streptococcus (GAS) had been identified in the swab sample [of person F]… [There was no indication in the records that F was isolated or what infection control measures were implemented.]

Example 35

…a consultant microbiologist contacted the medical team to report that Y's blood culture had grown streptococci, and that this might be Group A Streptococcus (iGAS) infection…[The next day the trust IPC team advised the ward staff that Y should be isolated to a side room, and Public Health England gave Y's close family advice on precautionary measures, including infection prevention and control information.]

Example 36 – Colchester Hospital

The blood cultures taken were positive and Group A Streptococcus was cultured, indicating an invasive GAS infection (iGAS). This was then confirmed on [date] and after discussion with a microbiologist, [an antibiotic] was prescribed, with advice to isolate R. [R's] relatives were given information on the iGAS infection and the reasons for R's isolation, as well as instructions for them to help prevent the spread of infection…[Records indicate that R was subsequently isolated in a side room.]

[R was admitted to hospital again approximately four weeks later, when iGAS was confirmed a second time.] R was appropriately isolated and [their] condition monitored because of the risk of cross-infection. (The records indicate that this isolation was not consistent; at times no side room was

available, and R was said to be on various wards. When R was in isolation, the records state that R preferred to have the door left open.)

From the examples available in the cases reviewed, there would appear to be inconsistencies in the MEHT's adherence to the local guidance on infection prevention and control, and on isolation of patients with infections. The review team were given conflicting accounts by MEHT staff about isolation practice regarding infected patients, and on how advice to staff on being vigilant about possible or potential GAS or iGAS infections in newly admitted patients was being communicated.

Findings

Communication to and between teams in the community, including healthcare workers in the ICT and in GP practices, seems at times to have been lacking in clarity and consistency. The result was that some community healthcare workers during the outbreak seem to have been confused about what infection prevention and control (IPC) measures they could or should have been following, or why they were required. This may have been because messages from the multi-agency incident management team (IMT) which included Public Health England (PHE) and Mid Essex CCG, were not entirely clear, not always passed on promptly or across the board, or because of incomplete monitoring of teams for understanding of and compliance with recommendations or directives on IPC. Timelines of communication have not emerged clearly, so it has not been possible for the review team to establish exactly when various IPC measures were to be implemented, or what they were. Record keeping in the community was not always thorough or consistent, and this has also made the picture about IPC practice and compliance during the outbreak unclear.

GPs were written to in April with a recommendation that district nurses swab patients with wounds; the review found only one case in which this recommendation was acted upon.

In hospital, guidelines would require patients with GAS and iGAS infections to be isolated. It has not been possible to establish whether or how consistently this was done in the cases reviewed. Personal protection equipment (PPE) appears to have been used in a few cases in accordance with local and national guidelines, but (as in the community) records do not clearly indicate how thoroughly, appropriately or consistently its use was implemented, and the review teams were given sometimes conflicting accounts about this matter from healthcare workers.

NHS England and NHS Improvement, Standard infection control precautions: national hand hygiene and personal protective equipment policy, March 2019, states that organisations must have*: systems and resources to implement and monitor compliance with infection prevention and control as specified in this policy in all care areas…To protect effectively against infection risks, SICPs [standard infection control precautions] must be used consistently by all staff. SICPs implementation monitoring must also be ongoing to ensure compliance with safe practices and to demonstrate ongoing commitment to patient, staff and visitor safety.*

It has not been possible at the time of writing to establish how the community and acute hospital organisations assure themselves that local or national IPC guidelines are being followed, or that their healthcare workers were receiving and acting appropriately on IPC measures to be implemented during the outbreak. Each organisation should review its infection prevention and control policies, including an updated infection outbreak management plan – or develop one if there is no such plan currently in place – that could be used in situations like the iGAS outbreak. Such plans should then inform a healthcare economy-wide plan for the area. This will ensure that professional practice is up to date. Such plans should ensure that an appropriate communication framework is in place to provide staff, patients and visitors with clear, consistent and timely information during outbreaks. Staff should also be given requisite training.

5.7 Record keeping

Record keeping is an integral part of effective patient care. It serves as a basis for planning and treatment. It aids the sharing of relevant information, is a means of communication between professionals, and is a format for describing the care a patient receives. It also aids the coordination and continuity of care.

In over half of the individual reviews, poor record keeping was identified to varying degrees in both the community, including GP practices, and in hospital services. These included information that was missing, poorly or illegibly recorded, partial or inaccurate, and there were gaps in the record keeping.

Example 37

The poor quality of clinical records in [the hospital] made it difficult to determine what care [person G] had been given, and what assessments had been made of [their] condition; for example, none of the risk assessments for [their] falls and pressure areas were completed. G's [emergency department] records contained minimal information, and there were considerable gaps in recording of G's observations.

Example 38

[Person E] had several episodes of not feeling well during this period, but records do not provide clear details. There is no mention of any red areas on [their] buttocks or of the condition of [their] leg following the GP's visit.

…the records do not show whether the [ICT] nurse informed the care home staff that E was at risk of developing an open pressure sore.

The care home records do not show any action being undertaken regarding the small breaks found on E's buttocks (such as whether they had dressings applied)

Good and accurate record keeping is a fundamental aspect of clinical care, as it documents the progress or deterioration of the individual and provides a contemporaneous record of clinical and care activity.

Example 39

There were two apparent inaccurate records in [person J's] notes. [The first related to an apparently inaccurate record stating that J was diabetic, and was administered with insulin to treat it; there is no reference in any of J's other records of their being diabetic. The second was a note apparently entered in error, relating to a completely different person's case]

This poor record keeping could have had a detrimental consequence for J's care, and there does not seem to be a record of any subsequent action taken, such as an incident report and medical review, regarding these inaccuracies.

Example 40

The clinical records were not always completed to a good standard…such as when a doctor visited [person E] some time on [date]: the record is not signed, dated or timed.

Example 41

…inconsistency in the recording of the care [person R] was receiving for R's leg wounds and confusion throughout the records between the right and left leg meant those who were treating R did not have a clear clinical picture of the wound(s)…It is unclear whether the site of the GAS infection was in R's right or left leg.

Example 42

There appears to be a misleading entry on the GP surgery clinical record system (SystmOne), which indicates that [person F] was allergic to [a

penicillin-based antibiotic]. It might have been more accurate to record that F was intolerant to it. [F was later admitted to hospital] The ambulance and ED records indicate that F had no known drug allergies…F was administered [the same penicillin-based antibiotic as above]. When it was later noticed that F's records indicated a penicillin allergy, F's antibiotics were changed.

Anomalies, inaccuracies and omissions of this kind across different sets of a person's clinical records could have a detrimental impact on their care and treatment. It should be noted in F's case, however, that no adverse reaction to the penicillin-based antibiotics administered was noted in their hospital records.

Example 43

There were five different areas [in hospital] where [person A's] care was documented, and this may have adversely affected handover and continuity. A clear clinical picture could not be viewed in one place as notes were recorded across a number of different clinical records/systems used by medical staff: nursing care booklets…[a] referral system, [a patient observations recording system], and sepsis guidance documentation.

In this case it is evident that a holistic picture of this person could not be referred to readily, and it is possible that important details in their history might have been unknown to medical practitioners treating them.

Findings

There are various examples over the thirteen cases where there are incomplete or inaccurate records (community, GP, care homes and in hospital) of an individual's medical history and treatment, and the care they received. The Provide 2018/19 Records Audit assesses the relative completeness of the electronic (SystmOne) recording system. The focus of this audit is mainly on demographics, and does little to reassure about the care delivered. For example, a care plan may have been completed, but the audit does not establish if it was completed

appropriately. In the community services, such records are often completed remotely by a registered nurse who may not have seen the patient in person. Therefore the record audit is of limited usefulness to the organisation from a quality perspective. As MEHT do not have an equivalent demographic style of audit, it is not possible to make a comparative comment. However, as record keeping is a fundamental aspect of patient care, all organisations should regularly undertake audits to assess the quality of their record keeping and identify ways to assist their staff in developing good record keeping skills. Because of the range of different recording systems in MEHT to document different aspects of care and treatment, a holistic picture is not always readily accessible. If clinicians have to access multiple recording systems to establish accurate information about their patient, this may hinder their capacity to make appropriate decisions and judgements.

Section 6: Supplementary observations

During this work the review team identified some matters in the thirteen cases reviewed which either lie outside of the scope of this investigation, or there was not enough information or data available on which to establish a definitive view, but which it seemed important to raise for organisations to consider. These are listed below:

- **Communication**

In three cases, communications and information sharing between health professionals were not effective, and in some places did not take place. In one case person Q had moved from one place of residence to another, and although this was recorded on the clinical information system (SystmOne), actions were not taken to ensure that their care plan was maintained. These omissions meant that the individual fell through the gaps in the system. There were four areas where the system broke down:

- The results of Q's wound swab taken as part of the iGAS outbreak, which indicated a GAS infection, were not passed on to Q's new GP
- The new care home and GP did not refer Q to the ICT for transfer of care
- Transfer of care between ICT nursing teams did not take place
- There was no follow up when the ICT nurse attended Q's previous residence and was told she had moved

Q did not therefore receive wound care, treatment for the GAS infection, or a health review for the last few weeks of their life, until their admission to hospital, by which time Q was very ill.

In the second case communication and information sharing between the various health professionals (ICT, out of hours, hospital discharge) was not effective. This along with the unintended consequences of their GP not being the first point of contact when person R was unwell meant that there was no single service coordinating the multi-disciplinary and multi-agency decision making in R's care.

The third case involved a GP request for a blood sample to be taken from person J, but the phlebotomist did not realise that this required a home visit. There is no record that the GP was informed about this, or that the mistake was rectified. The next time a blood test was requested was not until five weeks later. This might have delayed the identification of infection.

- **Delays**

In some of the thirteen cases there were delays in the community in the taking of wound swabs, particularly in one case where nine days elapsed before the requested swab took place. In other cases, there were delays in prescribed antibiotics becoming available or being taken; this could have had an adverse impact on the treatment for infection.

In Broomfield Hospital there were four cases where there were sometimes quite considerable delays in blood or swab samples being delivered to the microbiology department, and also in the results being made available.

- **Patient choice versus advice**

There were occasions when individuals whose cases were reviewed had preferred choices that were at variance with the clinical judgement of the nurses treating them, for example over the choice of dressings for wounds, equipment to support them or to mitigate symptoms. Some individuals found it difficult to comply with the advice they were given, such as keeping their legs elevated, or moving regularly (including lying in bed on alternate sides). This led to situations where their care plans might have been compromised. The organisations need to consider whether staff have clear guidance on when to escalate or seek further advice in these cases, or how their advice to patients can be enhanced in such a way that they understand the need for the measures they are being advised to follow. This might involve ways that alternative treatment strategies could be suggested or attempted.

- **Serious incidents/drug errors**

Organisations need to assure themselves that patient safety incidents, particularly concerning drug errors, are appropriately reported and acted upon.

- **Self-administration of medicines**

In one case, an individual who had been admitted to hospital was being treated with a specialist piece of equipment for the uninterrupted self-administration of medication. The nursing staff on the ward were not trained in the use of this equipment, and this individual's relative had to attend morning and evening to start and finish the automated medicating process. This relative also trained some of the nursing staff so that they were able, towards the end of this person's stay in hospital, to take over responsibility for using this equipment. The hospital's specialist team that may have been able to assist with this individual's medication needs were not involved. The hospital needs to assure itself that there are appropriate guidelines for staff on how to deal with this kind of situation.

Section 7: Conclusion

This independent investigation has been unable to identify a single source of transmission of this iGAS infection outbreak. Public Health England have subsequently informed the investigation that as a result of their epidemiological investigations, including Whole Genome Sequencing, there was evidence that people receiving community care in mid Essex, were at risk of contracting this particular infection. The organism (iGAS strain emm44) was isolated in a small number of staff in the community nursing team, and from a piece of community equipment. The transmission of this particular strain is likely to have been multifactorial and cannot be attributed to any single member of staff. This outbreak has had a significant impact on the community nursing teams, sometimes in an atmosphere of blame. They told the review team how difficult they had found it to continue delivering care in all cases as a result of the outbreak. This was often because of the constraints they were placed under as a consequence of infection prevention and control measures, and the demands of their caseload.

The Facere Melius clinical advisory board acknowledge that this has been a particularly distressing time for the relatives of the people who died, as well as for those involved with their care and treatment.

The individuals who died after contracting iGAS emm44 were all elderly, frail, and had underlying medical conditions; this made them particularly vulnerable to any infection. Nevertheless, it should be noted that some of these individuals still led active and full lives before they became seriously ill. As in most health care provision, there are areas of good practice and areas where improvement can be made. This investigation has identified that in some cases there were missed opportunities where treatment should have been more proactive, holistic and timely. These do not definitively indicate that their outcomes would have been different.

Section 8: Recommendations

As commissioners of this investigation, the Mid Essex CCG will want to ensure that the recommendations below are developed into a robust action plan, and continue to seek assurance and have oversight of their implementation by the relevant health and care providers.

8.1 Wound management

Recommendation 1

Non-registered practitioners should not undertake clinical tasks and assessments outside of their competence and/or training. Where non-registered staff have the competence for such tasks and assessments, appropriate supervision should be in place.

Recommendation 2

Non-registered staff should adhere to local wound management guidance, and have the competence to take and document appropriate basic observations when providing wound care, for example, recording wound sizes or photographing wounds.

Recommendation 3

Registered staff should undertake development and training to maintain evidence based, safe and effective clinical practice. Providers should ensure that such clinical training is regularly kept up to date and monitored for compliance.

Recommendation 4

All emergency and urgent care providers should ensure that they are fully and consistently implementing NICE guideline (NG51) on the recognition, diagnosis and early management of sepsis. Specifically, they should ensure that clinicians consistently carry out thorough clinical examinations to identify sources of infections, including the removal where necessary of bandages on wounds. Clinical teams should have access to the expertise and medical equipment to re-dress wounds in such cases, and to conduct necessary assessment and full body mapping.

Recommendation 5

Providers should ensure that their tissue viability services have the capacity and capability to provide a timely and responsive service that also maximises healthcare technology.

8.2 Identifying clinical deterioration

Recommendation 6

Providers across the whole health and care system should adopt the same National Early Warning Score, and act upon score indicators promptly and consistently.

Recommendation 7

Provide CIC should review the practice of registered nurses not routinely undertaking basic nursing observations and holistic person-centred assessment as part of their clinical interventions.

Recommendation 8

Community providers should ensure continuity of care to promote trust, confidence and quality in the service it provides. Specifically, on how they assure themselves that teams of staff are organised and deployed to achieve high quality care and enable the early detection of clinical deterioration.

Recommendation 9

All care homes should have up to date guidance and protocols in place to detect early clinical deterioration and have appropriate thresholds for clinical escalation.

8.3 Antibiotic therapy

Recommendation 10

There should be a clear set of guidelines on where and how clinicians record in a patient's documentation an adverse drug reaction, a drug intolerance/sensitivity or a true drug allergy. There should also be a system in place to ensure this information is consistently communicated and acted upon at hand over.

8.4 Infection prevention and control

Recommendation 11

The CCG working with local laboratories and Public Health England should establish systems for routinely notifying hospital and care providers when patients or residents have a positive infection status. This will enable the providers to enact the appropriate duty of care towards residents, patients and staff.

Recommendation 12

The CCGs and Public Health England should develop and implement a transparent, consistent communication strategy/plan to ensure that all those involved in providing care during an outbreak situation are fully informed and clear about their responsibilities and accountability.

Recommendation 13

There should be an economy-wide healthcare plan to respond effectively to an infection outbreak. Each organisation should review its infection prevention and control policies, including an updated infection outbreak management plan – or develop one if there is no such plan currently in place.

8.5 Record keeping

Recommendation 14

All health and care providers should undertake regular audits to assess the quality of electronic and hard copy records, and ensure staff follow professional standards and good practice in relation to the documentation of clinical records.

Recommendation 15

Those healthcare providers who use multiple record-keeping systems need to review these systems to ensure clinicians can access all accurate, holistic clinical information in real time to enable clinical oversight.

8.6 Supplementary observations

Recommendation 16

All provider organisations should have effective communication protocols and safeguards in place to ensure that the healthcare system maintains a consistent level of treatment and care for patients and residents who move between different health and care providers.

Recommendation 17

Healthcare providers need to review their systems and guidelines to minimise delays in taking of wound swabs or blood cultures where infection is suspected, and in results being made available to clinicians treating the individuals being tested.

Recommendation 18

All health and care providers should have clear guidance on how to support individuals who find it difficult to comply with the advice and guidance they are given.

Recommendation 19

All health and care providers need to assure themselves that their incident reporting processes are robust and that opportunities to learn and improve are maximised and completed.

Recommendation 20

Healthcare providers should have in place or review processes and guidance on how to manage patients admitted to their care who have a reliance on unfamiliar medical equipment to avoid interruption and/or maintain consistency in their medication.

Recommendation 21

All health and care providers should review key policies to ensure they are up to date and written in clear, unambiguous language. Policies that relate to the care provided in this outbreak include:

- Wound care management

- Escalation
- Deterioration
- Sepsis
- Infection prevention and control

Recommendation 22

All healthcare providers should have pre-determined processes to monitor directed deviations from and revisions to policies in response to healthcare situations such as infection outbreaks, where clinical advice and guidance is dynamically changing.