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Scottish National Blood Transfusion Service
Primary Care Leads
NHS Procurement Management SMT Leads

Copied:

Academy of Medical Royal colleges and Faculties
in Scotland
Chairs of SAMD and SEND
Board Resilience Leads
Incident Reporting and Investigation Centre,
Health Facilities Scotland
Chief Executive National Services Scotland
Chief Executive Healthcare Improvement
Scotland
Scottish Independent Hospitals Association

20 August 2021

Dear Colleague

URGENT Supply Disruption of BD Vacutainer Blood Specimen Collection Tubes

As you will be aware, Becton Dickinson (BD) advised a global supply disruption to the supply of four blood collection products, including three types of blood collection tubes used extensively across NHS Scotland. BD have reported the cause of this disruption is due to a combination of factors including increased global demand (driven by COVID) and the re-establishment of elective services.

While current stock levels in the National Distribution Centre are continuing to meet business as usual demand from NHS Boards, to respond to this, Scottish Government professional leads, NHS Scotland clinical leads and National Services Scotland have been working rapidly to put in place measures to alleviate any possible disruption to supply.

The enclosed Guidance "*Recommended Actions to optimise diagnostic testing during blood tube shortages*" is for use by NHS Scotland Boards, with separate guidance issued by NHS England. The Guidance has been developed by the NHS Scotland Clinical and Technical Reference Group (CTAG) with input from Scottish services, laboratory professionals, diagnostics networks, the Scottish Demand Optimisation Group and the Academy of Royal Colleges. Based on Realistic Medicine principles including our commitment to reduce waste



and plastics, this is to ensure demand optimisation and build on best practice in diagnostic test use.

A four country response to this issue has also been initiated with direct engagement with BD both at UK level and with National Services Scotland. Support is being provided to NHS Scotland through the National Supply Disruption Response System (NSDR) and mutual aid considered as necessary.

As the situation on supply remains ongoing, communication requests on supply issues should continue to be directed to the National Distribution Centre (NDC) as the NHS Scotland procurement is managed via National Procurement, with ordering direct from BD and distribution to the health Boards through the NDC who have set up a thrice weekly meeting with health boards.

Should it be necessary, any further updates to the guidance will be developed with health boards and shared through this process.

Thank you for your support as the remobilisation and sustainability of our services continues.

Yours sincerely

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Becton Dickinson Blood Tube Portfolio Supply Disruption.

Recommended actions for medical directors, nursing directors, GPs and laboratory services to optimise diagnostic testing during blood tube shortages.

18th August 2021

These recommendations are based upon recent guidance issued by NHS England¹ which benefited from input from clinical experts from laboratory service teams, primary care and acute care, including input from the Royal College of Pathologists (RCPATH), the Institute of Biomedical Science (IBMS), the Association for Clinical Biochemistry and Laboratory Medicine (ACB), Genomics Implementation Unit (NHSE) and the Academy of Medical Royal Colleges (AoMRC).

The NHS Scotland guidance is further tailored for Scottish services and has had input from laboratory professionals, diagnostic networks, The Scottish Demand Optimisation Group and the Academy of Medical Royal Colleges and Faculties in Scotland. The guidance was reviewed and recommended for implementation throughout Scotland by the national Clinical and Technical Advisory Group on 18th August 2021.

Background

A possible supply disruption in relation to Becton Dickinson's (BD) Blood Specimen Collection Portfolio has been notified for the United Kingdom (UK), although shortages are emerging worldwide. These constraints are due to increased global demand due to COVID recovery and a 3 week closure of the BD factory in Plymouth for performance of essential maintenance which had been delayed from last year. The factory is due to begin manufacturing again from the

evening of Sunday 15th August, ending their planned shutdown a week early, therefore supply will continue but at a constrained level.

The possible supply disruption mainly affects specific blood tube types, some of which are used across many NHS Scotland health board sites (see below). However, it may be likely that supply disruption could occur across a much wider portfolio of BD blood tubes and may impact blood tubes provided by other manufacturers as supply chains seek product suppliers. This disruption to supplies may be likely to last for several months but possibly longer.

BD Blood tubes (used across NHS Scotland) initially affected:

Type	Use
<i>Serum (SST) Yellow SST 5ml</i>	Used in more sensitive diagnostic testing (e.g. measuring the blood's proteins, lipids, hormones, electrolytes etc)
<i>EDTA Purple K2EDTA 4ml</i>	Basic haematology tube (used for identifying and counting blood cells, blood typing etc)
<i>Citrate Light Blue Sodium Citrate 2.7ml</i>	Used for coagulation and platelet function tests

Aims and objectives of this guidance

Considering potential global shortages of blood tube products (not just those from BD), this guidance is intended to apply to **every NHS Scotland site** irrespective of blood tube system being used and is aimed at smoothing and rationalising blood tube usage and optimising blood test ordering to ensure unnecessary testing is minimised.

As noted, the recommendations below are based upon recent guidance issued by NHS England (NHSE)¹ which benefited from input from clinical experts from laboratory service teams, primary care and acute care, including input from the Royal College of Pathologists (RCPATH), the Institute of Biomedical Science (IBMS), the Association for Clinical Biochemistry and Laboratory Medicine (ACB), NHSE Genomics Implementation Unit and the Academy of Medical Royal Colleges (AoMRC). This NHS Scotland guidance is further tailored for Scottish services and has had input from laboratory professionals, Diagnostic Networks, The Scottish Demand Optimisation Group and the Academy of Medical Royal Colleges and Faculties in Scotland.

The following recommendations should be implemented now where possible to ensure that a coordinated and equitable blood tube supply chain can be maintained and demand can be limited to appropriate clinically justifiable blood testing strategies. Separate actions are noted below for laboratory services, clinical services (as directed by medical and nursing directors) and supply lines. This guidance is subject to revision and will be updated if supplies of blood tubes are limited beyond the anticipated restrictions.

Scope

The following measures should be considered urgently by all medical directors, nursing directors, GPs, and laboratory services working with primary care, community and acute care providers within NHS Scotland. While outside the remit of NHS Scotland, private healthcare providers should also strive to maintain equitable levels of tube supplies and minimise unnecessary testing.

Overview and recommendations

The following recommendations are indicated for a variety of clinical and managerial groups. It is vital however that within each Health board, senior clinical and managerial oversight is established to take ownership of the actions recommended. Local communication strategies should be established to ensure the recommendations are understood and enacted by those responsible for each stage of test request through to laboratory analysis.

Actions for supply lines

The ordering and storage of blood tube supplies, both centrally and at the point of use, is distributed and managed differently within each health board. On a national basis however, procurement is managed via national procurement, with ordering direct from BD and subsequent distribution to the health boards controlled by the National Distribution Centre (NDC). This arrangement should continue to exist and there are measures in place to allow ordering and distribution to be continued and managed in the event that any specific shortage in BD supplies occur.

Health Boards should adhere to the following:

- Continue to order as before via the NDC rather than seek alternative supply routes or suppliers.
- Continue to engage in the meetings as called by National Procurement
- Maintain normal ordering levels and stockpiling of supplies should not occur.
- Ensure rotation of stock is optimised to reduce stock expiry resulting in unnecessary waste.
- Engage fully in attempts to provide stocktake data when requested; the number of tubes held centrally, at individual ward and at GP practice sites.
- Be prepared for calls to substitute specific tube orders for alternatives and for potential requests to remove from use tubes which are in short supply to enable fair distribution to other sites both within and across health boards.

Actions for laboratory services

For those laboratory services that are responsible for blood tube ordering, storage and distribution the actions above should be followed. Laboratory staff should engage fully with clinical users to ensure that best use is made of available blood tube supply and that blood test ordering is managed to minimise inappropriate requesting.

Laboratory services within health boards should, where possible, therefore:

- Work within the diagnostic networks to share information and input to decision making around tube selection, supply, and appropriate test ordering strategies.
- Anticipate requests to consider blood tube substitutions both from within existing blood tube types, other tube types within the BD range and those from other manufacturers. This will include efforts to assess clinical appropriateness and analytical suitability for their existing local analytical systems.
- Ensure accessible mechanisms exist for “add on tests” to existing samples held in the lab rather than necessitate additional blood tube usage. Tube storage times should be lengthened to extend the time window for add on tests.
- Work with laboratory users to minimise duplicate tube use, including exploring the possibility of tube sharing between departments. Changing tube type for some analytes to reduce overall tube use should be considered where possible (HbA1c, glucose, ethanol).
- Support point of care testing (POCT) services both in secondary and primary care, especially where blood tube use may be avoided by substituting a point of care test. Such point of care testing results should not need to be confirmed by the laboratory method. POCT reagent supplies may need to be increased.
- Samples that breach normal technical standards for acceptance should be retained and all possible mechanisms to avoid them being discarded should be explored. Patient safety remains paramount in such alterations of protocol, and the requirements to safely and positively identify samples remain.

- Ensure Laboratory professionals engage closely with local clinical services to provide advice and guide appropriate testing strategies based on these recommendations and taking local circumstances into account.
- Ensure laboratories closely monitor weekly rates of blood test ordering and tube usage if possible and report this information back to clinical users and centrally to national databases (Demand Optimisation teams at IMS) if requested.
- Review standard profiles for test groups with multiple tube requirements to consider separate profile by tube type.

Actions for clinical services

Work carried out by the Scottish National Demand Optimisation Group would suggest a significant amount of unwarranted variation in lab test use exists across Scotland. Many of the actions below represent currently advised good practice but given the possibility of blood tube shortages it is vital that changes in blood test ordering behaviour impact on the use of actual blood tube numbers being used rather than the number of tests ordered. Such change in practice needs to be driven by senior managers, clinicians, scientists and nurses, through their respective clinical teams to ensure blood tube use is reduced and that vital clinical services are maintained during this period of uncertain supply.

A strong culture of only ordering blood tests when absolutely clinically indicated should to be reinforced, especially when applied to repeat/routine testing.

1. Phlebotomy Services:

- Important that good stock control and rotation is maintained to ensure adequate supplies and minimal wastage due to out of date stock.
- Duplicate blood tubes should not be drawn routinely when multiple tests are requested.
- Requests for generic blood orders eg, every patient in the ward every day should be assessed by appropriate senior team lead (may be identified Phlebotomy lead at local level). Process to be detailed at a local level for phlebotomy staff to follow.
- Phlebotomy training for students should be minimised where safe to do so based on local risk assessment.
- Tube substitutions should only be made if explicitly recommended by the local laboratory so to ensure analyser compatibility.

2. Minimum Re-testing Intervals (MRIs):

- Professional body guidance on MRIs² should be always followed to ensure unnecessary repeat testing does not occur.
- The following increases in testing intervals should be considered if acute tube shortages are encountered:

Test/Profile	Situation	Re-testing Interval
Basic Biochemistry (U&E; LFTs)	In-patient monitoring	weekly if stable, otherwise every 3 days unless critically ill or critical result value/ trend needs closer monitoring (K+/new AKI).
Basic haematology (FBC)	In-patient monitoring	
Thyroid Function Testing	In-patient or community monitoring	2 months minimum interval for repeat monitoring
Vitamin D testing	Investigation or management of metabolic bone disease	Annual check. Random screening or testing related to simple vit D supplements should be avoided.
Vitamin B12 and Folate	In-patient or community monitoring	6 months for B12 / 3 months for Folate

3. Paediatric services:

- There is no current shortage of paediatric blood tubes and therefore laboratory testing in children should follow existing best practice protocols.
- Paediatric blood tubes should not be used for adult patients to avoid creating shortages in these tubes.

4. Point of care testing (POCT):

- Existing use of POCT should be maximised, especially when resulting in minimising unnecessary blood tube usage
- Central laboratory confirmation or checking of POCT results should not be necessary.
- Arterial Blood Gas machines frequently offer wide biochemistry and haematology repertoires. Such panel choices should be considered.
- Clotting tests, such as for INR, can also be done by POCT, especially in the community. Results should not normally need to be confirmed by a laboratory test unless out of analytical range of the POCT device or if there is significant clinical concern.
- Routinely checking hypoglycaemia result from POCT with a confirmatory lab blood glucose should be discouraged.

5. Clotting tests

- Shortages in BD light blue top sodium citrate tubes, commonly used for clotting tests, are likely to be encountered in the near future.
- A reduction in the ordering of unnecessary clotting screens is vital to ensure that blood tube stock can be reserved for more critical situations.
- Requests for blood D-Dimer testing should only be done in low risk patients, if fulfilling guideline criteria, to inform next stage of investigations. High risk patients should be considered for direct referral for imaging.
- D-Dimer POCT should not need to be confirmed by lab sample testing, and should be used for first line where available.
- Low-risk clotting screens pre-surgery should be avoided except in cases where bleeding risk is indicated, or clotting deficiency is suspected (liver dysfunction).
- Emergency department coagulation screening should be limited to bleeding and trauma presentation, patients on anti-coagulation, liver disorders, suspected sepsis and over-dose patients.

6. Primary Care:

- Due to the backlog in Primary Care as a result of the pandemic and the current capacity issues for phlebotomy, blood tests for patients with particular chronic conditions that have already been delayed should not be further delayed.
- Routine blood tests that are not already delayed should be avoided or delayed unless indicated by clinical concerns or where there is a suspicion of serious illness.
- Minimum Re-testing Intervals should be followed and considered for extension if clinically safe to do so.

7. Microbiology/Virology serology:

- Care should be taken to minimise unnecessary repeat testing, especially if a previous positive result has been obtained (i.e. HIV)
- Antenatal serology practices should be preserved.

8. Blood transfusion

- Requests for “Group & Save” should follow guidelines and be limited to those cases where blood transfusion is an expected outcome or where the need to know red cell antibody status is critical or the patient needs blood group confirmed on the “minimum 2 sample requirement rule” to allow safe provision of blood.

9. Genetic services

- Genomic testing is vital for unwell neonates, in prenatal screening and for cancer diagnosis. Stock should be used for these tests and should be prioritised accordingly to allow this testing to continue uninterrupted.
- Genomic testing should also be preserved where there is a specific implication on directing treatment, noting the impact on individual patients could be high.

10. Clinical research

- Clinical research studies that incorporate significant phlebotomy requirements should be considered for pausing. Exceptions may be those linked to new therapies or where it may impact direct patient treatments.

11. Advice to patients

- Patients may need to be reassured that they will not be deprived of appropriate clinically indicated blood test investigations as a result of these recommendations.
- Changes to previous test monitoring protocols should be discussed with individual patients when indicated.
- It is important to emphasise that tests will only be deferred where it is clinically safe to do so.

Reduction in specific clinical services

There is no requirement to halt specific clinical services at this time. If in the future blood tube supply is **severely compromised**, then pause of specific services or tests may be considered and supported locally with further guidance issued as required. The focus will be on preserving urgent and life-threatening services such as intensive care, acute admissions, cancer treatment and paediatric/maternity services. Pausing other less acute and elective work may need to be considered.

Halting or pausing any of the above clinical activity is not being advocated at this time but may be considered as a possible future contingency.

Ongoing Communications

Information regarding this situation will continue to be updated both from national sources and local health board based information. The information, recommendations and actions may need to be modified as the situation evolves. Discussions involving National Procurement and BD will continue on an ongoing basis, while clinical and technical advisory groups will meet regularly to assess the situation and modify clinical advice accordingly. Collaborative discussion with professional bodies and other similar strategic groups across the rest of the UK are ongoing.

Summary and Conclusions

The information and recommendations in this document are founded on the Realistic Medicine principles and provide an opportunity to establish innovative ways of working at this important time in the pandemic recovery. The suggested actions on tube ordering, laboratory processes and clinical decision making represent good practice and if followed should allow serious impacts

on healthcare delivery to be avoided. It is vital that all stakeholders work together to ensure efficient use of laboratory services and maintain the high levels of clinical care across all regions.

References

1. <https://www.england.nhs.uk/publication/becton-dickinson-blood-specimen-collection-portfolio-supply-disruption/>
2. https://www.rcpath.org/uploads/assets/253e8950-3721-4aa2-8ddd4bd94f73040e/g147_national-minimum_retesting_intervals_in_pathology.pdf

