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How to rely on the QMS during COVID-19

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Caring Expert Quality

Scope

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- Overview of how the QMS was used during the COVID-19 (C-19) pandemic (the impact on the QMS / the risk assessments / change controls / non-conformances etc.) and the role of QA
- The pace of change and how NHSBT was required to adapt
- What lessons were learnt and how the QMS can be used as a tool to tackle new risks (associated with C-19) or indeed any other unexpected events

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Role of QA and Impact on the QMS

QA Immediate response to COVID-19

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- Emergency QA Leadership Meeting 12th March 2020
- QA COVID-19 Lead nominated – SR
  - To lead QA response process
  - To attend C-19 related National Emergency Team (NET) meetings as QA Lead
- Reviewed MPD1400 – QA Emergency Triage (previously in use for EU Exit) for use in C-19 response
- Reviewed current workforce availability (including current A/L, future A/L, sickness, vulnerable staff)

QA's Key Principles

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As a Directorate, we want to come out of the COVID-19 response having learned, listened and changed to meet the changed requirements of our teams, customers and stakeholders.

1. Keep the wellbeing of our colleagues central to what we do, maintain focus on ensuring we are inclusive and that colleagues are supported to be the best they can be with their safety and the safety of our services and products as paramount.
2. Work to ensure we retain a strong level of compliance across our Safety Regulations and be willing to challenge where appropriate.
3. Listen to our customers and stakeholders and work to ensure our systems and processes are *user centric*
4. Maintain what we have learned throughout the pandemic – get the balance right where we can consider a better way of doing things

MPD1400 – QA Emergency Response Triage Process

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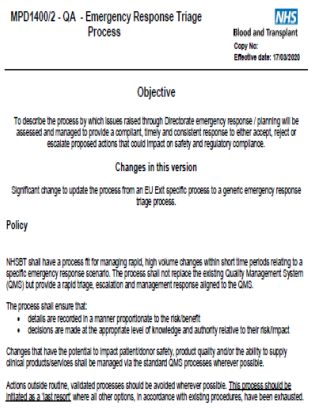
- Emergency process already in existence for EU Exit preparations; updated to change the process from an EU Exit specific process to a generic emergency response triage process
- Updated to reflect applicability to all emergency response scenarios, including C-19
- Process is primarily for managing rapid, high volume changes within short time periods relating to a specific emergency response scenario
- It does not replace the existing Quality Management System (QMS) but provides a rapid triage, escalation and management response aligned to the QMS.



MPD1400/2 - QA - Emergency Response Triage Process

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Copy No:

Effective date: 17/03/2020

Objective

To describe the process by which issues raised through Directorate emergency response / planning will be assessed and managed to provide a compliant, timely and consistent response to either accept, reject or escalate proposed actions that could impact on safety and regulatory compliance.

Changes in this version

Significant change to update the process from an EU Exit specific process to a generic emergency response triage process.

Policy

NHSBT shall have a process fit for managing rapid, high volume changes within short time periods relating to a specific emergency response scenario. The process shall not replace the existing Quality Management System (QMS) but provide a rapid triage, escalation and management response aligned to the QMS.

The process shall ensure that:

- details are recorded in a manner proportionate to the risk/benefit
- decisions are made at the appropriate level of knowledge and authority relative to their risk/impact

Changes that have the potential to impact patient/donor safety, product quality and/or the ability to supply clinical products/services shall be managed via the standard QMS processes wherever possible.

Actions outside routine, validated processes should be avoided wherever possible. This process should be initiated as a "last resort" where all other options, in accordance with existing procedures, have been exhausted.

MPD1400

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- The process ensures that:
  - Details are recorded in a manner proportionate to the risk/benefit
  - decisions are made at the appropriate level of knowledge and authority relative to their risk/impact - Changes that have the potential to impact patient/donor safety, product quality and/or the ability to supply clinical products/services shall be managed via the standard QMS processes wherever possible. Actions outside routine, validated processes should be avoided wherever possible.
  - This process should be initiated as a 'last resort' where all other options, in accordance with existing procedures, have been exhausted
- Process led by QA COVID lead supported by the nominated QA Emergency Response Team – QA Leadership Team (QALT)

QA Emergency Response Lead

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- Point of contact for the Directorate Function leads
- Assist with completion of the QA assessment form
- Maintain the SharePoint site
- Where required, assign issues to identified QA leads to complete detailed assessments, log the issue in the QA Share-point record
- Where required, and as a member of the QA Emergency Response Team, decide on immediate actions, acceptance of Directorate plans, escalation of Directorate plans for higher level approval or rejection, where they may impact on safety and / or compliance

QA Emergency Response Team

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- Provide support to the QA Emergency Response Lead for assessment and decision making on Directorate issues and plans, as required
- Deputise for the QA Emergency Response Lead, as required
- Help to maintain the SharePoint record, logging events into Q-Pulse if actions are to be risk assessed

MPD1400 process set-up

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- An overarching Change Control was raised in Q-Pulse
- A QA Emergency Response email inbox is operational and can be accessed by the appropriate QA staff
- An Emergency Specific SharePoint site was set-up
- An Emergency Response Tracker Spreadsheet was set-up (in SharePoint)
- The Organisational Emergency Response Team (usually a NET or Project Team) were informed early on that the process had been invoked
- Training in this process was provided to key individuals (including the Directorate Leads) by QA COVID-19 lead
- The QA Emergency Response Lead has been included in the relevant meetings/notifications
- A schedule of deputies is in place for the QA Emergency Response Lead and Team, as required

QA C-19 SharePoint Site

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- All QA documents related to the QA C-19 response are managed via this site, where they can updated and saved in real time by multiple people if required:
  - –Spreadsheets (Tracker, QA decision log, Equipment Management etc.)
  - –Risk Assessments
  - –Agenda / Minutes of SMT calls
  - –QA Resource Planning
- Access controlled and permissions managed

QA C-19 SharePoint Site

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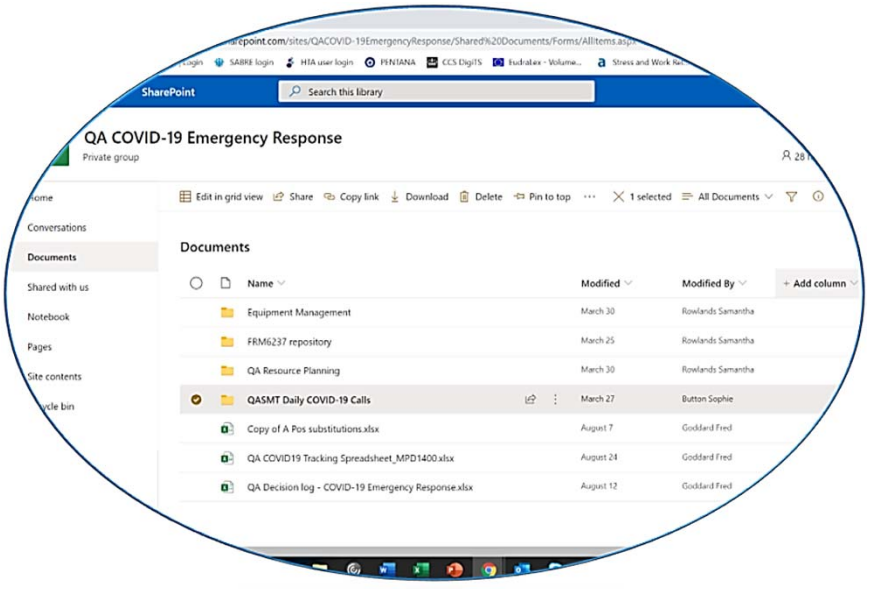

COVID-19 Tracker spreadsheet

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- Located within COVID-19 SharePoint site
- Used to document all COVID-19 related changes and Process Deviations (PDVs)
  - 215 CCs
  - 17 PDVs
- Each change is recorded within the tracker spreadsheet so that it is accessible to the full QA Emergency Response Team and any deputies throughout the duration of the Emergency Response.
- Weekly cross check re: what is on the spreadsheet and what is in the EQMS (Qpulse) to ensure all is captured in tracker
- Will be saved and uploaded into overarching CC once closed as a permanent record

QA Decision Log

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- Spreadsheet to log any QI discussion / decision not required to be raised formally within the QMS or logged on the Tracker spreadsheet; if the decision is referenced in QMS, it can be x-referenced here for transparency
- Located alongside Tracker spreadsheet in SharePoint

Directorate	Area affected	Date decision made	Decision made by	Description of decision	Rationale/Justification	Is decision recorded in QMS?	If yes, where? (include reference to INC/QI/CC/Document number if applicable)
E.g. Blood Supply	*What part of the process does decision refer to?*	*Xx/xx/xxxx*	*QA Staff member making / agreeing the decision*		*To include risk assessments etc.*	*Within an appropriate event record*	

Process summary

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a QMS overarching Change Control event will provide a marker in the QMS of how NHSBT are managing the Emergency Response plan assessments/requests

where a proposed plan is to be taken forward for implementation a separate QMS record, of the most appropriate type, will be raised (CC, PDV etc.)

the QPulse record number will be captured into the Share-point spreadsheet record to provide a link between the systems

at the end of the Emergency Response period a final version of the SharePoint spreadsheet will be attached to the overarching change control

Closure of process

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- The QA Senior Leadership Team shall decide at what point this process is stopped relative to the risk and information available. The decision shall take into consideration any changes made during the process operation phase that may need to be reversed to BAU in a controlled manner.
- Once the decision has been taken to stop the process, the contents of the Share-point site, including the Tracker and decision log spreadsheets, shall be reviewed and applicable documents will be copied across to the overarching Change Control record in Q-Pulse (EQMS) for retention. The Share-point site will be locked down thereafter so it cannot be altered.

Daily QA SMT Calls

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- Standard agenda for each meeting
  - –QA resource review and forward planning
  - –Feedback from Exec Team and COVID-19 NET calls
  - –Review of up to date Government and Organisational guidelines
  - –Updates on Tracker and QA Decision Log
- Allowed QA SMT to keep up to date with progress and action anything that had been escalated

Summary of QA's response

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- COVID-19 planning for the QA Directorate has been designed to support core operational frontline activity
- QA will ensure that we support Operational Departments to maintain regulatory compliance in the least burdensome way as possible
- QA must ensure that we are able to continue critical activities within the QA Directorate due to potential patient safety and regulatory compliance risks
- Support for Operational Directorates in relation to critical Quality activities and actions in line with MPD1400 (QA Emergency Response Triage Process)
- Working from home and meetings held virtually unless business critical

Impact on QMS

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Critical QMS / QA activities scoped at start of response

- Reviewed all QA activities that could potentially be paused to allow focus on COVID-19 response and planning for potential reduction in resource (due to sickness, movement to other areas etc.)
- Risk assessment performed and documented in relation to any activities that could be paused / modified to ensure that we could maintain assurance / compliance (i.e. Quality Review Meetings, Responsible Person walk-rounds)

Impact on QMS

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Updates to QMS further to Risk Assessment - examples

- Remote / desktop self inspections rather than on-site visits – QI raised to manage this process
- Remote monthly / bi-monthly Management Quality Reviews (MQRs) and weekly Quality Event Management cells (QEMs) to ensure compliance
- Deviations to Equipment management process (due to supplier/contractor issues etc.) – managed through overarching QI and logged on a spreadsheet on SharePoint
- Remote document reviews and sign-offs (e.g. TBTR, temp maps etc.) – new SOP created and using electronic format i.e. completion of forms electronically as much as possible with supporting email approvals and/or validated system approvals
- Operational activity QI's have been raised as needed and are monitored

Impact on QMS

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Change controls (CC) and Risk Assessments (RA)

- Logged CC events as soon as possible; this was sometimes in retrospect of activity happening - we subsequently created a map to be able to track them and logged on the Tracker spreadsheet
- There was a concern that we were not capturing everything in the QMS in real time and subsequently a statement as to why records were not going to be contemporaneous was written so we could explain / justify the approach given the balance of risk
- Overarching risk assessments have tracked completion of those events who are 'children' of it; therefore not all CCs have individual risk assessments and plans
- We have used several formats of risk assessment, some combine both the RA and Change Plan; it seems to work well and still fits with the QMS CC process which does not prescribe use of our controlled RA form
- We have used deviations to the CC plans as needed within the logged events (the approach and plan within activities changed on a daily basis) – this remained in line with our BAU CC process

Impact on QMS

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Impact on Regulatory inspections

<u>Medicines and Healthcare products Regulations Agency (MHRA)</u>

- UK competent authority
- No on-site inspections
- 3 remote / desktop MHRA inspections in June 2020
  - Will be followed up by 1-day on-site inspections in Nov 2020 (COVID-secure measures in place)
- Remote inspection for licencing of new site in Barnsley on 20th Oct 2020
- Remote assessment of all new CVP collection sites

Working example: CVP Collections

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- Utilised a standardised approach for all new CVP collection centres to cut down on workload and get the right focus on what needed to be managed
  - Also ensured consistency across sites / regions
- Using the National overarching change control risk assessment to create a generic donor centre risk assessment with the ability to add in local issues / risks, and a standardised action plan i.e. VAL236.
  - Adding all actions from RIA to the VAL and not additional documentation e.g. a checklist. Clear cross referencing between the two; we will be taking the same approach with decommissioning
- Maintained a communication stream between Quality project Specialists and regional operational QA colleagues

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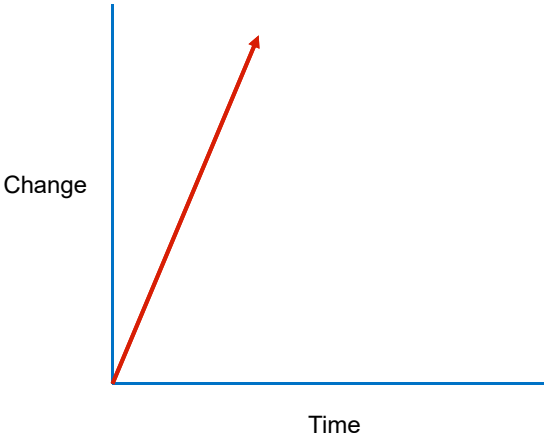
Managing the Pace of Change



Managing the Pace of Change

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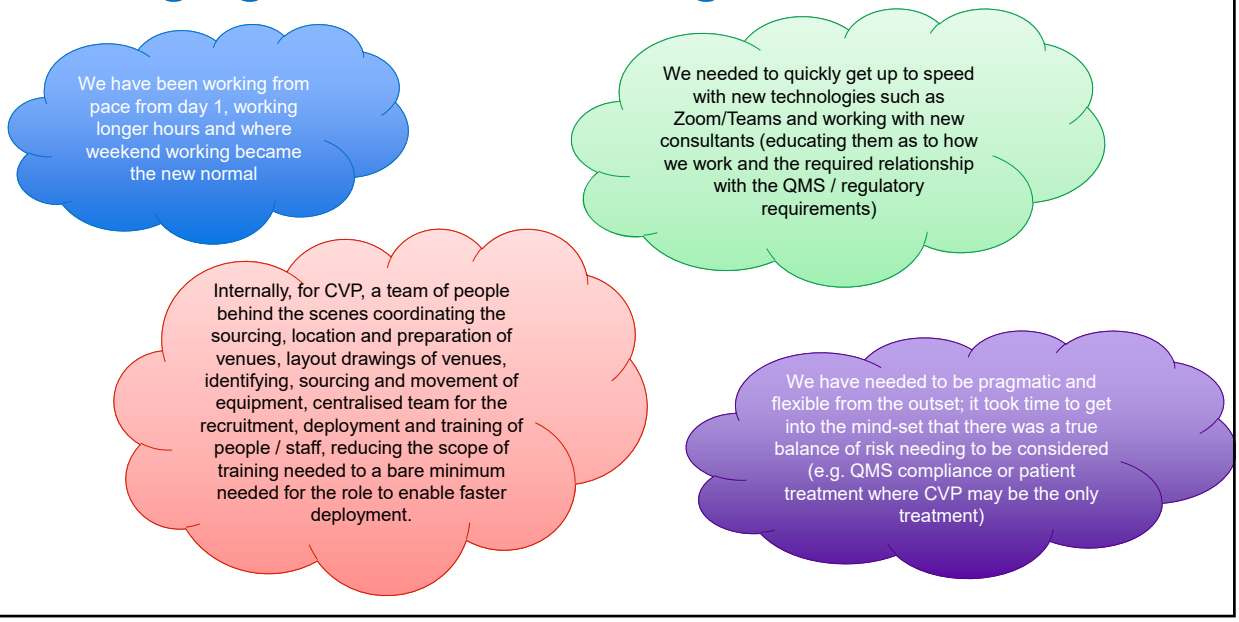

Managing the Pace of Change

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- Engagement with stakeholders internally – NET calls, daily SitRep input (help to understand what may become a risk)
- Early dialogue / engagement with the MHRA / CQC has been key on setting out / agreeing an approach for new CVP collection venues, licence variations & possible derogations which has subsequently developed into a good working relationship
- Pragmatism of MHRA and willingness to react accordingly – main single point of contact Inspector at MHRA who agreed requirements. Consistency of communication updates with the Inspector helped with facilitation of the licencing section to process variations quickly.

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Lessons Learned

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Lessons Learned

- Have QA at the top table from the outset; in the initial stages we seemed to be on the fringes of the Leadership and decision making
- The workstreams were siloed to start with; cross stakeholder working has been key and it took time to get the message across that QA must be a stakeholder
- Having the correct lead people organising the workstreams who have the requisite knowledge and understanding both strategically and operationally
- Able to bring in dedicated and expert / knowledgeable / experienced bank staff (ex NHSBT) who could focus on organising processes, coordinating with other teams, writing RIAs and VAL docs etc. which frees up operational QA to do their BAU activities and oversee the local changes as they are implemented.
- Important to not forget those in QA who have not been directly involved with Covid work and who may have initially felt ‘side lined’; without the support of the wider QA team (such as QA Ops, QA Direct) we would have failed

Lessons learned

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- Flexible QMS and flexible QA Support
- Emergency Response Document drafted and trained out prior to emergency situation
  - –Also had Pandemic Plan and Business Continuity Plans in place
- Consider recovery throughout to ensure reversal possible when pandemic response is parred back
- Learning to be comfortable with being uncomfortable
- In truth, we are still learning and as we look to the second Phase of the Programme there is a lot of work ahead e.g. 14 new CVP collections centres

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"This organisation has achieved amazing things since the start of the pandemic. Not only have we maintained business as usual activities in the most challenging of circumstances, but we have supported the wider national response by ramping up one of the world's largest convalescent plasma programmes from scratch. This £100m programme represents a five-fold increase on NHSBT's normal annual change portfolio - challenging the organisation to deliver at a scale and pace that we haven't had to before"

Betsy Bassis (Chief Exec, NHSBT)