Guidance for inspectors:

Transitional Monitoring Activity

Version 1.1 – September 2020

Contents

Transitional Monitoring Activity

Summary

Our focus over the last few months has naturally been on the immediate risks presented by the pandemic. We stopped routine inspections and developed the Emergency Support Framework. We know that this needs to evolve.

As part of our Transitional Regulatory Approach, we are taking forward the technology and some elements of how the ESF worked, building on the benefits of a structured approach to monitoring and stronger relationship management. We are taking a wider and more robust view of risk. Our Transitional Monitoring Activity will have clear areas of focus, based on a subset of our existing Key Lines of Enquiry (KLOEs), with an emphasis on safety, access and leadership. They include elements of all five key questions. This monitoring will enable us to be more targeted and responsive to risk. We will have flexibility to build in other areas of focus as we develop this approach.

The purpose of Transitional Monitoring Activity (TMA) and the TMA App is to provide a structure for inspectors to gather and consider information about any risks and whether further regulatory activity is needed at this time. The process starts with information gathering and review, and is followed by a conversation with registered or NHS managers where needed. The inspector then uses a five point scale to score the risk level for each TMA KLOE.

The experiences of people who use services, their families and carers are central to this approach. We are trialling improvements to how we and Experts by Experience gather people's experiences at all stages of the TMA.

This guidance covers prioritising locations / services for monitoring calls, using the TMA App to support Teams calls with location / service managers, risk scoring the TMA KLOEs, and when further regulatory activity is indicated.

Introduction

1. Purpose

1.1. Our Transitional Regulatory Approach is flexible and builds on what we learned during the height of the pandemic. The key components are:

- Transitional Monitoring Activity (TMA), a strengthened approach to monitoring, with clear areas of focus based on existing Key Lines of Enquiry (KLOEs), to enable us to continually monitor risk in a service
- Use of technology (the TMA app) and our local relationships to have better direct contact with people who are using services their families and staff in services

- Inspection activity that is more targeted and focused on where we have concerns, without returning to a routine programme of planned inspections at this time.

1.2. There will be an internal and external engagement plan to ensure that colleagues, care workers, providers and the public are aware of and inform continuous improvement of TMA.

1.3. TMA combines organising information we already hold (including about people's experience of them) with structured monitoring conversations supported by the TMA App. All locations / services / trusts will be considered for a TMA call, with call prioritisation based on data and intelligence.

1.4. TMA calls are not inspections (and do not rate services). Their purpose is to help us understand current risks and, where needed, target regulatory activity. The outputs will be added to the information we hold about quality and safety in locations, services and trusts.

1.5. The TM App is a monitoring tool to help structure our assessment of the level of risk in a location, service, or NHS Trust. It builds on the technology and learning gained from the Emergency Support Framework (ESF). Like the ESF and IPC applications, the TMA relies on structured conversations using Microsoft Teams or phone calls rather than site visits. It will be used in ASC, PMS and NHS trusts and independent healthcare. Careful planning combined with inspectors' professional judgement is particularly important.

2. Monitoring principles

2.1. The first step in the TMA process is for inspectors to review the information we already hold about the location / service / trust. They will also decide what other information we need to form an up to date view about people's experiences of care. If we have all the information we need to score the risk level for each TMA KLOE we may not need to make a call.

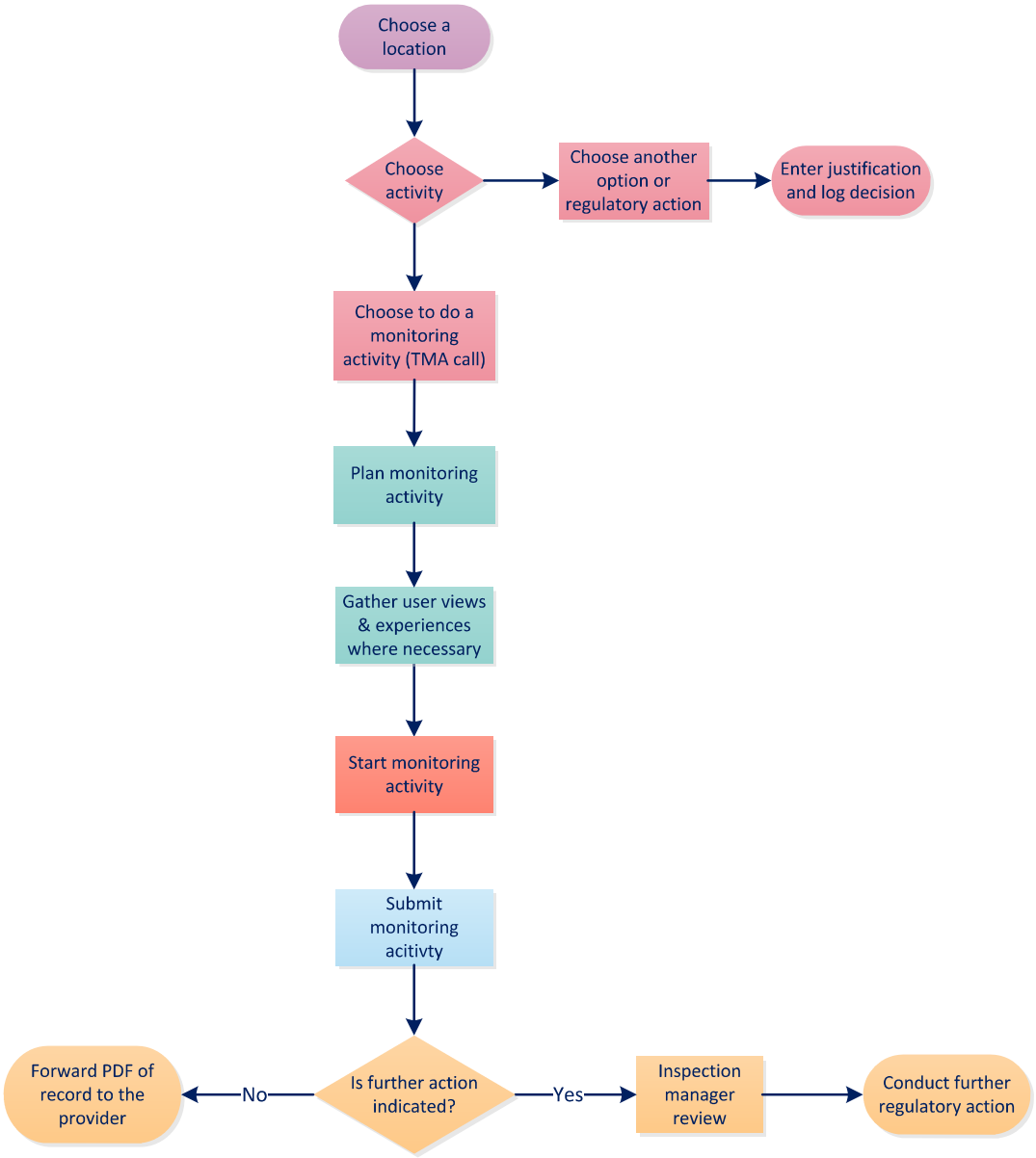
2.2. TMA calls are structured conversations with providers who are individuals and manage their own service, registered or NHS managers, or (in certain services), or a suitable person nominated by them (for example, GP practice managers). They are an opportunity for you to explore, understand and record:

- Any risks to service quality that people using the service are currently experiencing
- How the location/service/trust is responding to key risks to people who are using the service
- How the risks are being managed and whether there is a need for further regulatory activity, such as an inspection and/or enforcement processes
- How the provider develops solutions to difficult problems – we are interested in finding, understanding and sharing good practice and innovation.

The phrase ‘registered or NHS manager’ is used throughout the rest of this guidance but includes providers who are individuals and manage their own service, and alternatives such as GP practice managers where inspectors agree that this is suitable.

2.3. You need to plan a TMA call carefully. If we already hold recent information about the location / service / trust, you should use this to help build a clear understanding at the first stage of the process. You should ask for further information only where there are gaps and avoid any duplication. The information should help you decide the risk level for the KLOE in question. You need to exercise professional judgement when requesting evidence and ensure that the location/service/trust shares it in a secure way, either during the call or shortly afterwards.

3. High level TMA process chart



There is a more detailed process chart at Appendix 1.

Using the Transitional Monitoring App

4. Sector specific guidance

4.1. The TMA and its App use a subset of our existing key lines of enquiry. We will follow them to explore how people experience services, safety risks, access, and leadership. TMA KLOEs for the different sectors are very similar but have variations where needed to reflect their particular circumstances.

4.2. There are sector specific guidance documents that include appropriate prompts for different service types to support using the TMA app in the different settings we regulate:

- Adult Social Care
- Independent Health, initially independent dialysis services, ambulance services and learning disability and autism services
- NHS Trust level
- PMS including NHS GP services, independent health providers of primary care services, urgent care, out of hours and NHS111, and primary care dental services
- Service specific guidance will be available at a later date for Children's Homes, NHS Ambulance services, Health and Justice and NHS Core Services

5. The five-point TMA risk scale

5.1. We will record the level of risk at a service or location, for each TMA KLOE, using this five-point scale:

1 = Very High	Issues require immediate attention
2 = High	Issues require attention
3 = Medium	Some Issues require attention
4 = Low	Few issues currently identified
5 = Very Low	No issues currently identified

(You can select 'Not Applicable' in the app, where needed)

5.2. The risk levels you select will be a proportionate judgement about the level of risk across the topics and practice areas covered by each TMA KLOE, informed by the prompts set out in the sector specific guidance. They will also take into account the provider's awareness of the risks and issues, their track record, and their capacity to recognise, respond to and learn from relevant events.

- Scores of '**Very High**' or '**High**' in any KLOE mean that there are serious risks and/or issues at the provider / location / service or trust, and the TMA outcome is that a further regulatory response

is indicated. An MRM will be arranged to decide what it will be, urgently where needed.

- Scores of '**Medium**' in one or more KLOE normally mean that the TMA outcome is that no further activity is indicated at this time, but see section 5.3 below.
- Scores of '**Low**' or '**Very Low**' mean that that TMA outcome is that no further regulatory action is indicated at this time.
- 'N/A' means that a KLOE is not applicable to the location / service / NHS trust in question.

5.3. Where there are no 'Very High' or 'High' scores in any TMA KLOE the normal TMA outcome is that a .pdf summary report is generated for sending to the provider. Sending a .pdf means that no further regulatory activity will be initiated at this time.

But…

Where a location or service is scored 'Medium' in one or more TMA KLOE(s)

And…

Moderate harm or disproportionate restrictions of liberty or loss of human rights are possible

Inspectors will use their judgement about whether the level and nature of the risks and issues involved are sufficient to recommend to their IM that the TMA outcome is changed, a summary is not sent, and an MRM is arranged to discuss a proportionate regulatory response. The kind of response will depend on the circumstances involved. Examples include follow up TMA calls and referrals to / engagement with sources of support such as local councils and CCGs.

6. Risk level criteria

Very High

Major harm has occurred or is probable.

High

1. Major harm to people is possible, or
2. Moderate harm is probable, or
3. Disproportionate restrictions of liberty or breaches of human rights are probable

Medium

1. Moderate harm is possible, or
2. Minor harm is probable, or

3. Disproportionate restrictions of liberty or breaches of human rights are possible

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Low

1. Minor harm is possible, or

2. Minor restrictions of liberty or infringements of human rights are possible

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Very Low

There are no known or anticipated urgent, major, moderate or minor risks and issues at this location.

Harm definitions

Major harm:

Harm posing a serious risk to life, health or wellbeing including:
- permanent disability
- an irreversible adverse condition
- inhumane or degrading treatment of people
- significant infringement of a person's rights or welfare (of more than one month's duration); and/or
- major reduction in a person's quality of life.

Moderate harm

Harm that would result in:
- temporary disability (of more than one week's but less than one month's duration)
- a reversible adverse health condition
- significant infringement of any person's rights or welfare (of more than one week's but less than one month's duration); and/or
- Moderate reduction in quality of life.

Minor harm

Harm that would result in:
- significant infringement of any person's rights or welfare (of less than one week's duration); and/or
- minor reduction in quality of life
- minor reversible health condition.

Disproportionate restrictions to liberty and breaches of human rights

Cultures, restrictions and behaviours leading to:
- systematic or frequent unlawful, inappropriate and unnecessary detention and deprivation of liberty
- the regular use of inappropriate restraint

- failure to ensure that people and/or their supporters are aware of their rights when detained / deprived of their liberty
- people experiencing unnecessary daily limitations on choice and control over their lives, care or treatment, with decisions not being taken in a way that meet the MCA and MHA and their Codes of Practice
- unlawful, profound and systemic discrimination in relation to protected characteristics

Minor restrictions to liberty and minor breaches of human rights

Restrictions and behaviours that have led to:

- occasional use of unlawful, inappropriate and unnecessary detention, deprivation of liberty
- use of restraint of a temporary and occasional nature
- inconsistency in informing people and/or their supporters about their rights when detained / deprived of their liberty
- blanket restrictions without apparent justification that could limit choice or quality of life for service users, but do not pose an immediate risk of significant harm
- people experiencing minor, unnecessary limitations on choice and control over their care or treatment and wider lives of a temporary and occasional nature that are not in their best interests and/or least restrictive if they lack mental capacity to consent to them.

Preparation

7. Prioritising services for TMA calls

7.1. It is important to remember the reasons for TMA, which are:

- to support a consistent approach to considering risk which is not based on previous ratings alone,
- to ensure a clear audit trail of the monitoring and risk assessment process,
- to support a focus on safety, leadership and access
- to help to target any subsequent regulatory response on key risks within a provider or a service

7.2. Review locations / services in your portfolio.

- Review each location / service and prioritise them for a TMA call using the prioritisation score on the locations page of the TMA app. Prioritisation scores are automatically calculated using the location / service's regulatory history and other data in our systems.
- Use local knowledge if there is no prioritisation score, within sector timeframes. NHS trusts have no trust level score. Also use

core service prioritisation scores to inform your trust level prioritisation and planning.

- If there is no feedback about people's experiences of care make sure you build in time to gather it.

8. Exemptions

8.1. Certain circumstances could delay or make a TMA call unnecessary. The following circumstances are listed in a drop-down menu in the App; inspectors should select them as needed:

- An immediate regulatory response is already planned – for example, an inspection will take place within two months.
- The service / location is dormant (inspectors should follow the CRM process for this)
- A tribunal is planned; inspectors should check with the legal team concerned.
- Where enforcement action is being contemplated or planned, or is subject to appeal we need to proceed with caution. Inspectors should not ask questions specifically relating to planned or ongoing criminal investigation as this will normally need to be done in a PACE interview. We can still ask questions about general regulatory matters. Inspectors should check whether TMA calls should proceed in these circumstances with their legal advisor.
- A recent inspection, for example within the last month, means there is no current need for a TMA, depending on the scope of the inspection.

8.2. A recent ESF conversation is not a reason to delay carrying out a TMA call; ESF calls had a different purpose and focus. ESF calls were supportive conversations with locations / services designed to help us better understand safety and risks associated with the emergency pandemic period. The scope of the TMA is wider, and helps us to decide whether an inspection or other regulatory response is needed.

9. Arranging calls

9.1. Most TMA calls are 1:1 conversations, but if registered or NHS managers want to invite two or three other colleagues to join in, they are welcome to do so. Careful planning of TMA calls is important if there are several people involved. Where the location is of a service such as a GP practice it may be better for the practice manager to represent the service for some or most of the call. Inspectors should discuss this with relevant registered managers and agree suitable arrangements.

9.2. Inspectors will contact registered or NHS managers to agree dates and times for TMA Teams calls to enable both to make the make best use of their time. There is no standard or required notice period for

TMA calls. Managers should not need more than a week or two's notice, less if they and inspector are happy with that. Inspectors will then send a Teams meeting invitation email with the agreed date and time. The length of TMA calls will depend on the size and complexity of the service / location / trust and other factors. You should normally allow one to two hours, some may need longer. Particularly long calls should include regular breaks, and where needed inspectors can suggest and agree second calls.

9.3. Teams meeting invitations give invitees a telephone number that can be used in the event of broadband or network problems, or of participants don't have access to the internet. Inspectors should make this clear to the registered or NHS manager by adding the following text to the calendar invite email:

> You can join our meeting on line by clicking on the **'Join Microsoft Teams Meeting'** link below. If you already have Microsoft Teams in your system you will be able to use it.
>
> If not, you will be given the option to download the Teams app to your system, or you can join the call using your internet browser (preferably Chrome or Edge). Either method will work.
>
> If you are unable to join online you can dial in by telephoning
>
> [redacted]
>
> Then enter the conference ID xxx xxx xxx (*copy from the invite*) and # when asked to do so, using your phone's keypad.
>
> ---
>
> Join Microsoft Teams Meeting
>
> [redacted] United Kingdom, London (Toll)
>
> Conference ID: xxx xxx xxx#
>
> Local numbers | Reset PIN | Learn more about Teams | Meeting options
>
> CareQuality Commission

10. Planning and making TMA calls

10.1. Careful planning of TMA calls is essential to ensure that discussion is focused on the most important areas. Only request evidence from locations / services / trusts if we do not already hold the information and it is proportionate to do so.

10.2. On the TMA app Activity page, click on ‘New Activity’, and:

- Choose ‘Monitor’ from the drop-down box.
- Click on ‘Next Stage’ and it will take you to the ‘Plan Monitoring Activity’ page.
- Make sure the ‘Background Information’ tab is selected. This page has space for you to enter short summary information about:
  - An overview of the service
  - Its inspection, enforcement, concerns and ratings history
  - Information from sources not covered elsewhere on the page
  - Feedback from staff, professionals, commissioners, Healthwatch and similar
  - Feedback from people who use the service and their families / carers / supporters
- The app has separate sections for recording information and feedback about people’s experiences of care gathered before and after TMA call planning. ***Existing*** user voice is information held in our systems before TMA planning began. ***New*** user voice is information gathered after TMA planning and call activity began.

  After entering your existing user voice summary you will use a drop down to categorize both the ‘before’ and ‘after’ user feedback as ‘*positive*’, ‘*negative*’ or ‘*both positive and negative*’.
- Click on the ‘Questions’ tab, this will open the TMA KLOEs pages. The TMA KLOE pages can be used for planning as well as recording information received during and after your TMA call.
- Summarise what you already know about the service in the KLOE sections in advance of the TMA call. This includes relevant information in feedback from people who use the service, staff and other stakeholders. It is important to add known concerns to the relevant KLOE section(s). This will ensure the people’s views are captured before the TMA call and help to both shape conversations with providers and influence risk decisions.
- Your sector specific guidance will include prompts with sub-questions for each KLOE
- Click on the ‘Evidence’ tab. Attach or link relevant documents and information we already hold in this Section. If the information is stored in CRM (for example from the ESF or routine monitoring) cross refer to it.
- Refer to the guidance in sections 5 and 6 on scoring and assign a risk level. Complete each of these and Save.

10.3. When making a TMA call click ‘Next Stage’ again to access the ‘Start Monitoring Activity’ section. You still have access to the ‘Background information’ ‘Questions’ and ‘Evidence’ tabs.

- Add information gained during the call to relevant KLOE fields in the ‘Questions’ tab.
- Attach or provide a link to documents and information you are sent during or after the TMA call in the ‘Evidence’ tab.
- Add any feedback gained from users, their families and supporters during or after the call to the ‘New user voice’ section under the ‘Background information’ tab, and categorise it as ‘positive’, ‘negative’ or ‘both positive and negative’.
- Refer to the guidance in sections 5 and 6 on scoring and assign a risk level to each KLOE.

10.4. KLOE text boxes in the ‘Questions’ tab are limited to 4000 characters/approximately 500 words, so avoid copying and pasting detailed data from CRM or other sources without summarising it first.

10.5. **Remember to keep Saving as you go along.**

10.6. ‘Submit monitoring activity’ is where you see the App’s Suggested Outcome which indicates a further regulatory response or no further regulation.

10.7. As a result of learning from the ESF, the overall risk level in the TMA takes into account individual KLOE scores. If one KLOE has a High or Very High-risk level, this will indicate a further regulatory response

10.8. You can set out your reasons for changing a TMA outcome, with a justification, by clicking on the ‘Change Outcome’ tab. Your Inspection Manager would need to approve this decision, and this would happen outside the App.

10.9. The next page is to draft and submit a Summary Record. You should only share the Summary Record with managers where no further regulatory action is indicated.

10.10. The Summary Record is your account of key points of the conversation and your conclusions about risk. The Summary Record will automatically generate a PDF which will be emailed to you when completed.

10.11. After sharing with the Inspection Manager cases where further regulatory response is needed, you should keep the summary record on file in CRM if it is needed for an MRM.

11. Closed cultures

11.1. Review the closed cultures guidance on the Intranet. You can read it here. You should be familiar with this guidance before making TMA calls. Where appropriate, you should also consider information held by Mental Health Act Reviewers and how this can inform the TMA.

11.2. Any service that delivers care can have a closed culture. A closed culture is a poor culture that could lead to harm, and potentially includes infringements of human rights such as abuse. During the pandemic there is more risk that a closed culture will develop,

because of external social contact being limited under IPC arrangements. You should consider the risk of a closed culture at the location or service you are calling. Characteristics of a closed culture include:

- Staff and/or management no longer seeing people using the service as individual people.
- Few if any people being able to speak up for themselves. This could be because of a lack of communication skills, a lack of support to speak up, or fear of abuse.

11.3. Other warning signs may include poor experiences of care, use of restrictions, restraint, segregation and seclusion, poor physical environment, poor skills, experience and training of staff, weak management and leadership and lack of external oversight.

11.4. These characteristics may mean that people who use the service are more likely to be at risk of harm. The harm can be deliberate or unintentional. It can include abuse, human rights breaches or clinical harm. This means that as an organisation we must make extra efforts to understand their experiences.

11.5. We can make sure we gather people's voices through different ways:

- Speaking to people who use services
- Speaking to the family and friends of people who use services
- Using enquiries on CRM, including safeguarding, whistleblowing, incidents and deaths
- Qualitative reviews and findings from thematic analysis of findings from enquiries and other sources of information such as whistleblowing, complaints and feedback on care. Briefings are being developed for independent hospitals (Learning Disabilities and Autism) and for residential and community Adult Social Care services
- Give Feedback on Care
- Complaints and concerns
- Speaking to staff, advocates and visiting agencies
- External agencies such as local authorities, commissioners, Healthwatch and NHS England/Improvement.

12. People's Experiences of Care

12.1. Where we are proceeding with a TMA call but there is little or no evidence about peoples' experiences of care, planning must include how we will gather more evidence about this.

12.2. Where we cannot make a reliable assessment of risk because of lack of information about people's experiences of care, we will consider whether an inspection is required, even where no TMA KLOE has a score of 1, 2 or 3.

12.3. You could:

- Ask the registered or NHS manager to share information about people's experiences that they have gathered, together with information about how the information was collected – inspectors will need to make a judgement about how reliable the information is.
- Ask the registered or NHS manager to promote our online Give Feedback on Care form, and to give our national NCSC contact details to service users, their families, friends and community contacts. Ask the registered or NHS manager for evidence that they have done this.
- Ask registered or NHS managers about any existing resident / patient / carer / user groups and any other local community / advocacy groups we can make virtual contact with to ask for feedback about the location or service.
- Contact the local Healthwatch team and ask them for any information they hold about people's experiences of the service and any other local community / advocacy groups, as above. See more on the Regional and Local Public Engagement page on the intranet.
- Contact user and other groups via email or telephone. Inspectors can also set up virtual groups and 1:1 discussions for gathering feedback using Teams or by phone.
- Use CQC's Experts by Experience (Ex by Ex) programme which can offer support with contacting people who use the service and/or local community/advocacy groups. Please request ExE involvement via Cygnum early in the process to allow sufficient lead time. Guidance on how to make requests is available on the intranet: Ex by Ex virtual support.
- Refer to guidance on the Intranet about undertaking local public engagement to hear people's experiences of care.

12.4. When planning this activity, consider whether there are particular groups of people using the service who might be at a higher risk of poor care and prioritise engagement with these groups. Where appropriate, consider information that Mental Health Act Reviewers gather and how this will inform the TMA.

12.5. Summarise feedback from users of services or patients while planning activity on the App

12.6. We are piloting other ways of hearing the views of people who use services. The pilot will also include evaluation of the methods described above. We will update the TMA and this guidance as we learn from and develop this work.

Gathering and recording information

13. Evidence gathering and storing

13.1. TMA calls are enhanced monitoring activity around risk, not performance assessments. They explore the TMA KLOEs in full, as set out in the service specific guidance. Where needed, you should ask for relevant, focused evidence to understand and illustrate the themes, risks, and improvements covered in the call.

13.2. We do not want to add any unnecessary burden on services / locations / trusts, so any requests for evidence should be proportionate. We should only ask for evidence if we do not already have it, for example from people who use services / patients, system partners and intelligence sources. You also have access to information gained in previous inspections and calls. Where you are unable to make clear judgements about risk using information that we already hold, you should ask the service / location / trust to provide relevant additional evidence. Please refer to the sector specific KLOE guidance linked in 4.2 above for further detail.

13.3. Don't ask for all the evidence examples in the sector and service guidance. Use your judgement to identify the evidence you need to corroborate findings and assess each KLOE's risk level.

13.4. Initial analysis and planning will help you decide on the specific evidence you need, rather than allowing registered or NHS managers to submit selected records and other documents of their choice.

Submitting evidence

13.5. Registered or NHS managers should supply evidence during the TMA call. They can do so by screen sharing, but if a copy of a document is needed providers must send it securely (encrypted or with password) via email. If they cannot supply evidence during the call it should be sent to us within 24 hours. You can apply professional judgement about accepting password protected evidence outside this timescale.

13.6. An alternative secure way for providers to send large numbers of documents is by using the Global Scape SFTP system. You can read guidance about using Global Scape here. However, the TMA process and calls will not normally include requesting large amounts of evidence, so carefully consider the appropriateness of using Global Scape.

Evidence storage and recording

13.7. Evidence should be logged and saved using the agreed standard CQC naming convention.

13.8. There is a free text box for summarising the evidence you have reviewed within the TMA app. Evidence received from the location / service / trust or other sources is saved in the TMA app.

Sign off

13.9. Inspectors will discuss all locations with KLOE risk scores of 1: Very High or 2: High with their Inspection Manager, to decide what our regulatory response will be. See the timescales in section 17 below. This will take place outside the TMA App.

13.10. Please see section 5.3 above where there are any risk scores of 3: Medium.

13.11. If further regulatory action is possible or likely, do **not** inform the registered or NHS manager before we have decided on what course of action to take; we may decide to do an unannounced inspection. If we are asked about the outcome in these circumstances, you should say that we are still considering the information gathered before reaching our decision.

14. Electronic recording of TMA calls

14.1. You should not normally record TMA calls electronically using the audio / video recording facility in Teams. If exceptionally the registered or NHS manager wishes to do so, they must only do so openly and with the consent of the people on the call. We would have to meet all GDPR requirements and our recording would be subject to FOI requests. We do not encourage the recording of TMA calls.

14.2. Do not offer Zoom as an alternative to Teams. We do not have a licence for this.

14.3. Registered or NHS managers may want to record the calls themselves. Again, we discourage this as not being appropriate for what is a routine call between us. Where they insist on recording a TMA call you can consider steps to mitigate any concerns you have with your manager. For example:

- If a Teams call is likely to be recorded, you are entitled to turn off your camera (you are entitled to do this anyway).
- CQC can also make a recording (e.g. if we are concerned that a recording may be edited or manipulated). You must confirm to those on the call clearly and openly that you are doing so.
- Expressly remind the people on the call that the data collected from the recording is subject to General Data Protection Regulation (GDPR) and seek assurance from the people making the recording that the data will be used fairly and responsibly in accordance with GDPR.
- Where you have particular concerns about being recorded, a colleague could make the call instead.

14.4. If you become aware that a location/service/trust has unexpectedly started recording a call that is under way, and if you are uncomfortable with this and they refuse to stop, you would be justified to stop the call so that you can discuss the next steps with your manager.

TMA outcomes and next steps

15. TMA Summary Records (ASC and PMS services only)

15.1. Only locations/service where no further regulatory action is indicated will receive a summary record.

15.2. Please note Hospitals services (IH and NHS) will not be sent a summary record. This will be reviewed following evaluation.

15.3. TMA call summary records are limited to 4000 characters (about 500 words).

15.4. The TMA app produces a copy of the inspector's summary record as a PDF. The PDF is automatically emailed to the inspector when complete, using a standard format. The Summary Record is a concise account of the TMA call in the inspector's own words. If no further regulatory activity is indicated, inspectors will email a copy to the registered manager, the nominated individual or the service manager.

Summary Record writing principles (**where no further action is needed**)

- Show the date of the conversation and who was present.
- Start the text with 'You shared the following information with us' and briefly list your findings for KLOEs where relevant.
- List any action that the service has agreed to take.

15.5. If no regulatory response is indicated, inspectors will send the summary to the service / location with a standard letter.

15.6. **If further action is indicated**: summary records will show a precis of the risks and refer to relevant evidence. The circumstances should be discussed with Inspection Managers and at MRMs as needed, depending on the sector scheme of delegation. Inspectors will prepare for MRMs in the usual way, completing a decision tree tool where needed, and storing information and evidence in CRM.

15.7. Summary Records and risk levels are stored in the TMA app. Outputs from TMA monitoring calls will inform future regulatory planning.

15.8. The TMA process is not an inspection and the Summary Record is not an inspection report, so processes associated with inspection reports such as the factual accuracy step do not apply.

15.9. We do not publish Summary Records on our website. They are a record for us and the location / service. We are currently exploring the best way of publishing information about TMA outcomes on our website.

15.10. Information we record in the TMA process that we do not share with providers is subject to Freedom of Information requests, including from third parties.

16. Where we have serious concerns

16.1. Where information or calls lead to concerns about actual or potential avoidable harm, abuse, neglect and breaches of human rights, we will hold an MRM to decide our regulatory response, for example inspection or enforcement processes.

16.2. Our response to serious concerns must be proportionate to the risks involved, follow existing sector processes, and ensure that where needed we and / or appropriate partner agencies act quickly to keep people safe.

16.3. Where risk scores are 1: Very High, 2: High or 3: Medium the principles in 5.2 will apply. Where there are equality, diversity and human rights issues, inspectors will take into account our public sector equality duty when considering the need for a regulatory response. Further guidance is available in our Equality and Human Rights FAQs or from the equality and human rights team via [redacted]

Response timelines

- Where any KLOE is risk scored 1 major harm is occurring or probable. We will inspect the service or hold a MRM to plan next steps, and/ or alert system partners such as the police and local authority safeguarding teams **within a maximum of 24 hours**.
- Where any KLOE is scored 2 we will hold a MRM to plan next steps **within a maximum of 2 working days**.
- Where any KLOE has scored 3 and the inspector and IM have decided to change the TMA outcome because further proportionate regulatory activity is needed, we will hold a MRM to plan this **within a maximum of 5 working days**.

N.B. Normal sector risk management and MRM arrangements remain in place at all times, irrespective of TMA processes and risk scores.

17. Where no further action is necessary

17.1. Where a location/service has no Very High or High risks, and we decide that no immediate action is required in relation to Medium risks, the TMA summary record will be shared with the location/service (ASC and PMS only)

18. If we do need to take regulatory action

18.1. No summary record will be issued to the location/service. This is important as we need to be able to allow for unannounced inspections. You will meet with your Inspection Manager to decide on appropriate action.

18.2. A decision to set up an MRM or that further regulatory activity is indicated should be recorded in CRM, in line with sector schemes of delegation

19. Enforcement

19.1. Where we decide to take enforcement action we will follow existing CQC and standard sector schemes of delegation.

19.2. Any MRM will take place in the usual way, outside the App, and will be recorded in CRM.

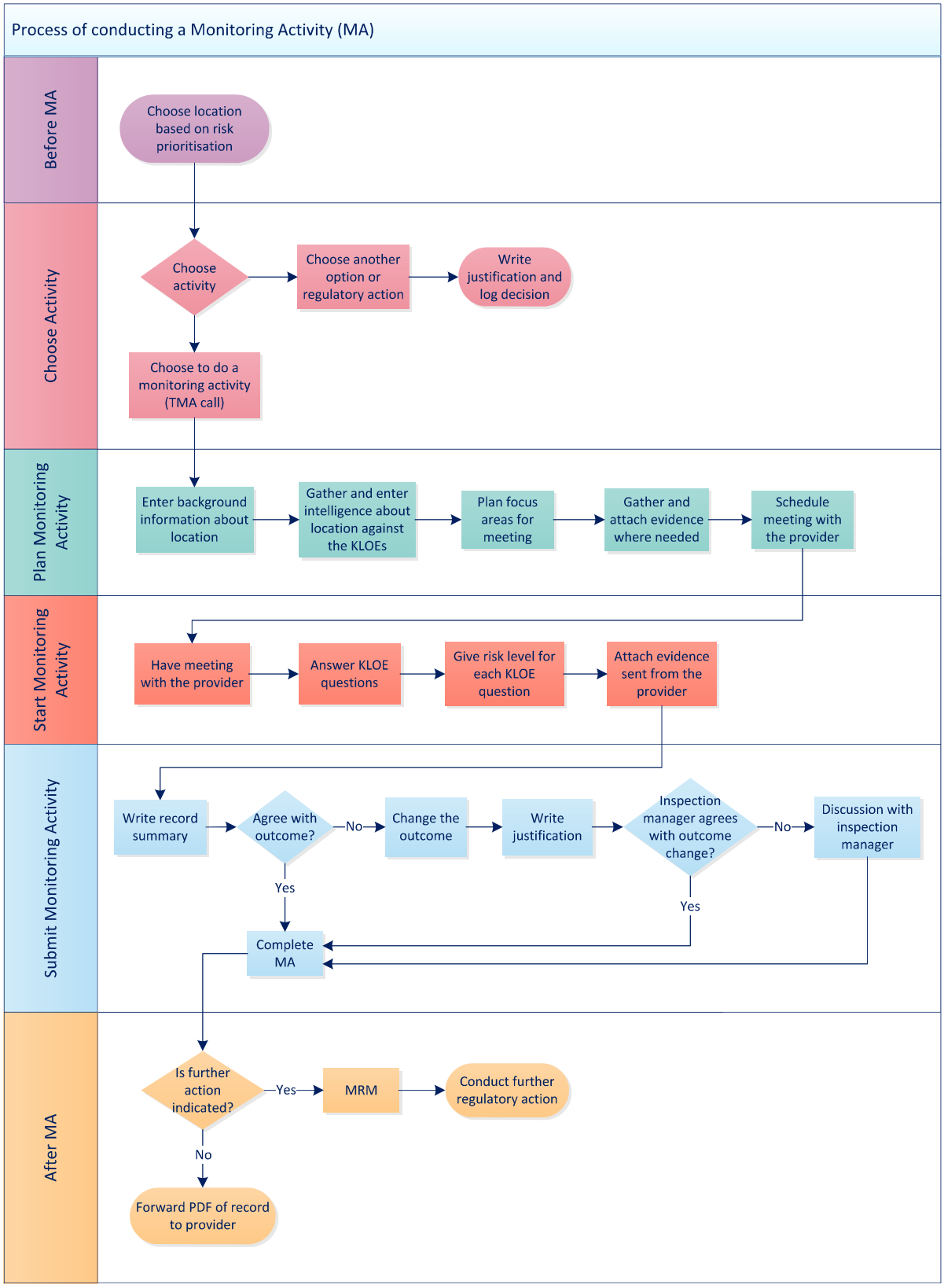
20. Website banner

20.1. We are still considering how to publicly communicate the outcomes of TMA calls. The TMA Summary Record is currently a private record of the monitoring conversation to be shared between the CQC and the service/location.

21. Refusal to participate

21.1. TMA calls are undertaken by consent. Our response to a refusal to engage with a TMA call will be considered at an MRM.

Appendix 1: Detailed TMA process chart



Appendix 2: Applying the 'scoring' framework

1 = Very High Issues require immediate attention
2 = High Issues require attention
3 = Medium Some issues require attention
4 = Low Few issues currently identified
5 = Very Low No issues currently identified

Inspectors will need to use their experience and judgement when applying the risk framework and deciding the score for each KLOE.

We will add to this appendix of additional guidance on TMA risk scoring in response to experience and feedback from inspectors.

The harm levels quoted in Section 6 of the guidance are aligned with the impact levels in the enforcement decision tree and the NRLS codes for degrees of harm. Section 6 also includes information on scoring in relation to disproportionate and minor restrictions to liberty and infringements of human rights.

Scores of 1 (very high risk) should be recorded where 'Major harm' has occurred or is probable.

Major harm is that which poses a serious risk to any person's life, health or wellbeing, including:

- Death
- Permanent disability
- An irreversible adverse condition

Major harm is irreversible and has a profound, permanent and very serious impact on a person's life, health and wellbeing. This includes avoidable death, brain damage, loss of limbs, permanently and seriously limited range of movement, and paralysis.

Scores of 2 (high risk) should be recorded where 'Major' harm is possible, 'Moderate' harm is probable, or where disproportionate restrictions of liberty or breaches of human rights are probable.

Moderate harm is that which leads to significant but reversible injury, including for example:

- Temporary disability (of more than one week's but less than one month's duration)
- A reversible adverse health condition

- Significant infringement of any person's rights or welfare (of more than one week's but less than one month's duration); and/or
- Moderate reduction in quality of life.

Moderate harm is significant but not permanent. Examples include unexpected or unintended incidents that result in the need for medical treatment, the possibility of surgical intervention, and the cancellation of treatment. For example, broken limbs; serious sprains, concussion; serious infections not causing permanent harm; and serious but not permanent injury to soft tissue.

Scores of 3 (medium risk) should be recorded where 'Moderate' harm is possible, 'Minor' harm is probable, or where minor restrictions of liberty or infringements of human rights are possible.

Minor harm is that which causes a minor reversible health condition. Examples include harm caused by an unexpected or unintended incident requiring extra observation, and home-based treatment to minor cuts, bruises and sprains.