Emerging concerns protocol

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1. Introduction

Health and social care professional and system regulators, and others with a role in the quality and safety of care provision have an essential role in ensuring that services promote, protect and maintain the health, safety and well-being of people who use services, and in protecting the public. As a group of organisations, we expect providers and professionals to work together to provide the best possible care. We hold ourselves to the same standards. We know that sharing concerns at the right time can make it easier to make links between pieces of information that tell us a problem is emerging. Information sharing between organisations does happen. However, at times this sharing can be inconsistent and too slow to prevent people receiving poor care.

We believe that we can strengthen the systems that allow this information to be shared and improve the transparency about our work for people receiving care, professionals and health and care providers. Doing so will allow us to fulfil our collective role better, as well as improve our ability to fulfil our individual roles. We also believe that working together more effectively can reduce unnecessary burden. For example, we can do this by encouraging our organisations to develop joint plans when we share similar concerns, or by taking assurance from each other's actions.

2. Background

This protocol was developed under the governance of the Health and Social Care Regulators Forum (the forum). All of the partners who have signed up to this protocol share the common objective of ensuring that health and social care professionals and systems across the UK serve to protect the public, whilst maintaining the health, safety and well-being of the professionals themselves, those using services, families and carers.

In October 2016, the forum convened a meeting of professional regulators, system regulators and other partners to discuss how working together as a safety system could support the delivery of high-quality care. One action from the meeting was to develop a protocol for regulators, which would help them share information about emerging concerns with each other and system partners in a timely fashion. This would include information that might undermine or harm the reputation of the professions or the regulators and their registrants, and particularly information that caused ongoing concern but may not be shared under existing arrangements.

The following organisations are signatories of this protocol:

- Care Quality Commission
- General Pharmaceutical Council
- General Medical Council
- Health and Care Professions Council

- Health Education England
- Nursing and Midwifery Council
- Local Government and Social Care Ombudsman
- Parliamentary and Health Service Ombudsman

In addition, the following organisations are working with our emerging concerns working group:

- General Dental Council
- NHS England
- NHS Improvement

3. Purpose of the protocol

The purpose of the protocol is to provide a clearly defined mechanism for organisations with a role in the quality and safety of care provision to share information that may indicate risks to people who use services, their carers, families or professionals. This might include:

- situations that may not be seen as an emergency, but which may indicate future risks
- cultural issues within health and social care settings that may be noticed, but would not necessarily be raised through alternative formal systems.

The objective is to be flexible and empowering, supporting regulators to understand how they **can** share information. This protocol is designed to work alongside protocols that already exist. However, it is specifically aimed at helping staff across the signatory organisations to make decisions about when to escalate information of concern with one or more organisations. It is not intended to work against good working relationships that already exist, but to strengthen and encourage good practice.

4. Principles of the protocol

The following principles have been agreed across all organisations acting as signatories:

- The organisations involved should work to model an open culture in which staff can speak up about concerns

- The organisations involved should be transparent about how the protocol is used, whilst maintaining confidentiality of content (in all directions, including the National Quality Board, providers, public, registrants)
- The organisations are explicit about confidentiality agreements and parameters (including working with information shared by third parties)
- The organisations involved shall maintain and respect individual organisation's executive autonomy
- The protocol must work within the law, including any restrictions on information sharing that are included in each signatory's statutory role
- The protocol should be short and simple, with a focus on feasibility
- The protocol will be developed through a collaborative, partnership approach between organisations
- No issue will be too small for an organisation to consider using the protocol
- The model developed should be linked to other tools in the system such as the Quality Risk Profiling Tool and existing Memoranda of Understanding.

5. Organisational roles and responsibilities

Organisational responsibilities

Each of the organisations signed up to the protocol has a responsibility for responding to concerns about care provision. These organisations all have an interface across health and social care and a role in ensuring that those who use services, their carers and families receive high-quality services from professional staff and registered health and social care organisations. One of the aims of establishing this protocol is to provide guidelines on how to raise and escalate concerns that may not be seen as an emergency, but which could indicate a future risk. It aims to enable discussions to take place safely and without judgement, and decisions to be made as to how relevant concerns can be addressed in a **proactive** rather than a reactive way. It does not replace existing responsibilities and arrangements for taking emergency action, including arrangements for whistleblowing and responsibilities under Duty of Candour and Fit and Proper Persons Regulations.

6. Who is involved and when?

What is the process?

This protocol establishes a process for earlier sharing of concerns, and for discussions between partners that might be of relevance to them. It aims to facilitate sharing of this information at an early stage, so that links between concerns can be made, and a wider system view of the issue can be established. These concerns may fall into three categories:

- concerns about individual or groups of professionals
- concerns about healthcare systems and the healthcare environment (including the learning environments of professionals)
- concerns that might have an impact on trust and confidence in professionals or the professions overall.

The process of using the protocol is set out in Section 7. Any organisation that is a partner in the protocol can initiate use of the protocol. The protocol deliberately does not set out an exhaustive list of the situations in which it should be used. However, in deciding whether a concern fits the purpose, Annex D proposes a series of questions to support the decision. Once a decision is made that information of concern appropriate for the protocol is to be shared, the organisation holding the information contacts other relevant partners (which may be some or all of the signatories), records the relevant information and arranges a Regulatory Review Panel (RRP). This panel is a newly established panel, which uses a template agenda given later in this protocol. It is an opportunity for key persons from each organisation to hear and share information. The intention is that this conversation helps to develop a picture of the concern, and also to facilitate a shared understanding of the appropriate, coordinated intervention. The RRP does not have specific legal powers as a panel, and is instead a voluntary group established by the signatories. Individual signatories retain their respective powers and restrictions under their own legislation, which allows members of the RRP to take appropriate action.

Safeguarding

Any organisation may receive information that indicates that abuse, harm or neglect has taken place. Any form of abuse, avoidable harm or neglect is unacceptable. Each organisation has procedures for managing these types of concerns and they must be followed. Each individual organisation remains responsible for ensuring they follow their own internal safeguarding procedures. Nobody should wait to activate the protocol instead of acting on safeguarding concerns – immediate action should always be taken where necessary.

Learning environments

Professional education is delivered in clinical learning environments within a broad range of health and social care settings and involves partnerships with service deliverers themselves and higher education institutions. Assuring the quality of education for both undergraduate and postgraduate learners therefore brings the professional regulators into contact with health and care settings. Although the professional regulators are looking at the quality of the clinical learning environment and the quality of care, they should pass on any wider concerns about a setting to other professional regulators, the system regulators, or other partners where relevant. Similarly, where an organisation receives a rating of inadequate or requires improvement, CQC should ensure the professional regulators and other partners where relevant are aware of this, so consideration can be given to the adequacy of the education and learning arrangements and environment.

How does this fit with other structures and arrangements in place?

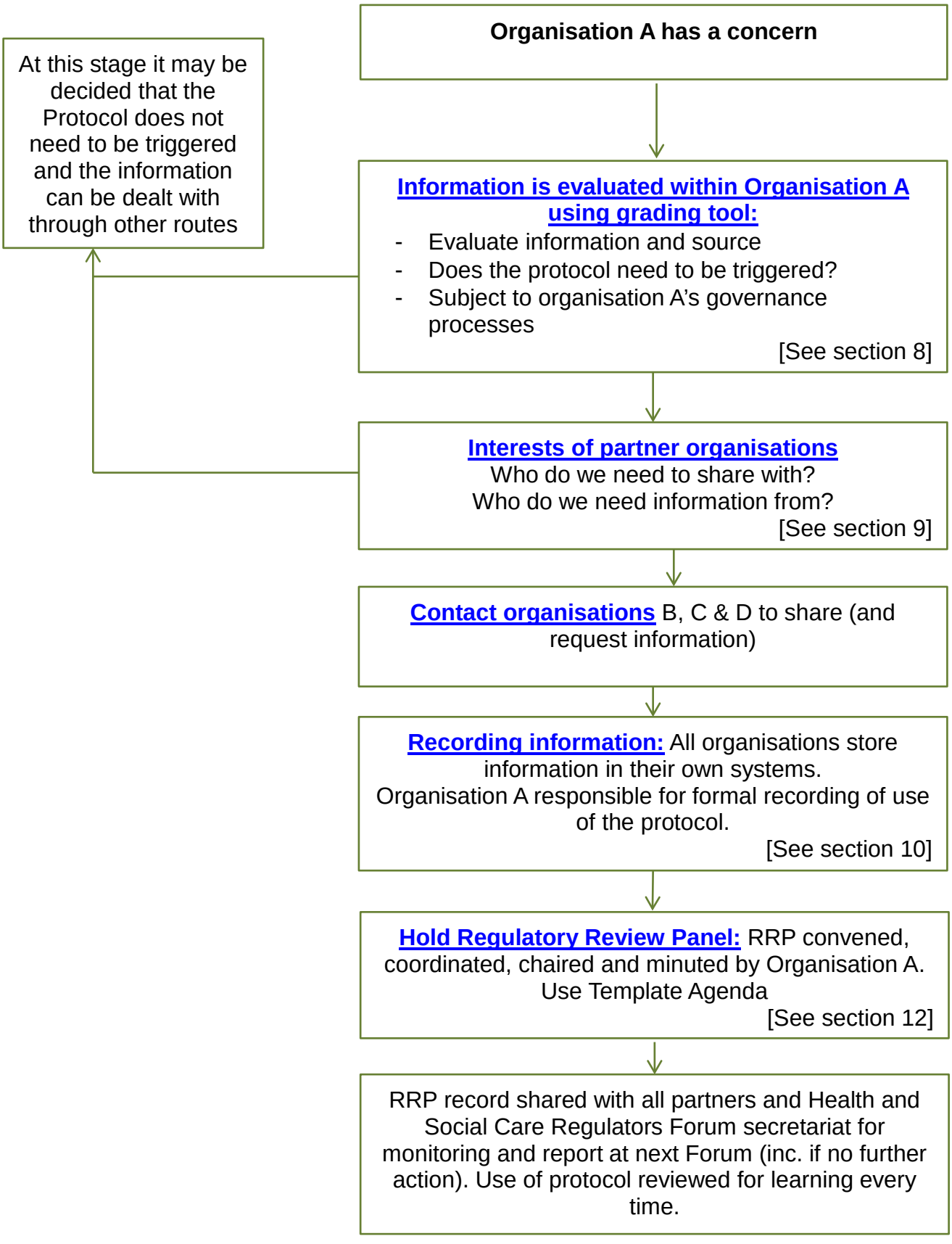
This protocol does not prevent the continued work of other agreements and arrangements in place between its signatories. For example, organisations will continue to use specific Memoranda of Understanding they may share. Specific meetings and agreements between signatories will also to continue to function as they have previously, including but not limited to:

- Joint Strategic Oversight Group
- Dental Services Programme Board
- GMC/CQC Joint Working Group
- General Practice Board
- Quality Surveillance Groups
- NMC/ CQC Joint Working Group

This protocol provides a support mechanism and agreement that enables each organisation to share emerging concerns and pull together a cross-organisation panel, when:

- this is the most appropriate response, and
- there are not other mechanisms in place to ensure the right people are able to have the right conversation at the right time, and
- the emerging concern is not being sufficiently managed via other arrangements or structures.

7. Emerging concerns protocol summary diagram



8. Grading tool – review of information within organisation a

Where information is provided by a single individual, it should be scored on three criteria. This supports consistency and helps the receiving organisation(s) make decisions about how to use the information. Decisions are made by organisations on a case-by-case basis, and are not determined by this scoring. The three criteria are:

- evaluating the source
- evaluating the information
- protecting the source.

Where information does not come from an individual, the grading system need not be used.

Evaluating the source

Source grading	Source	Characteristics
A	Highly credible	Has or should have access to systems, data, information that would corroborate or substantiate the matter. There is no reason to doubt the veracity of what has been shared.
B	Existing contact, who has previously provided credible information	Has previously provided information that is accurate 60% to 90% of the time. There is no concern with the motives for passing on this, or previous information.
C	Existing contact, who has previously provided credible information some of the time	Has previously provided information of mixed reliability but there are no concerns about the motives of this person. The information has been accurate more than it has been inaccurate (51% accurate or above).
D	Existing contact – unreliable	Reserved for contacts who have provided unreliable information more than once OR there is significant doubt about their motivation. Their accuracy rate is below 50%.
X	Unknown / untested / single individual / general concern	It is impossible to assess the accuracy or otherwise of the information provided.

Evaluating the information

Source grading	Source	Characteristics
1	Absolute	Aware that the information is known to be true: can be corroborated by more than one source.
2	Primary	Witnessed by the source and can be supported by others present.
3	Secondary	Not witnessed by the source, but they are aware that there is secondary evidence
4	Unknown	Cannot assess because it would be unlawful/ inappropriate/impractical, or it is known that there is nothing that corroborates the information
5	Not credible	Information is thought to be false

Protecting the source

Note: the grading given in this section is given for information and to reflect any expressed wishes of the source. It does not determine whether information needs to be shared. The identity of the source should only be shared between organisations where this is necessary and proportionate. In some circumstances, an organisation may consider it necessary to disclose information about the source under discretionary powers or responsibilities, or in response to statutory requests, notwithstanding the wishes expressed by the individual(s) who provided the information.

Source grading	Source	Characteristics
1	Full disclosure	Can be shared externally, no redaction, no reference needed
2	Partial disclosure	Can only be shared if redaction occurs to protect the source
3	Unrestricted internal dissemination	Unrestricted internal circulation can occur; third party disclosure should not occur
4	Restricted to specific	Can be shared with specific nominated staff across regulators
5	Fully restricted	Cannot be shared

9. Determine how to use protocol

Organisation A reviews the list of interests of each partner and identifies those that are relevant. This may in some cases be all partners.

Interests of partner organisations

Care Quality Commission (CQC)

CQC would request contact about:

- Any concerns and relevant information about a health or adult social care organisation in England which may call into question its registration with CQC.
- Any concerns and relevant information about a health or adult social care organisation with regard to the quality of care or safety for people using services.
- Information from any investigation that raises concerns about poor team working, leadership, record keeping, appraisal systems or general failures at a health or adult social care organisation in England.

General Medical Council (GMC)

The GMC would like to be informed of emerging or urgent concerns that may present a risk of harm to patient safety or undermine the public's confidence in the medical profession.

The nature of concerns we are interested in include:

- Concerns about an individual doctor's fitness to practise
- Concerns about an individual's doctors registration and revalidation
- Concerns about the quality of medical education or the healthcare systems or environment in which doctors are trained

System concerns which may be of interest to the GMC include to the following:

- Staffing levels and supervision of trainees
- Management / leadership
- Equipment and premises
- Patient safety reporting systems

Further details and examples of the types of issue the GMC is interested in hearing about can be found in the GMC's operational protocol with CQC. A copy can be

found on the GMC / CQC web sites or upon request by emailing the GMC's single point of contact.

General Pharmaceutical Council (GPC)

We would like to be informed of concerns, including emerging concerns, about pharmacists, pharmacy technicians and registered pharmacies that could suggest there is a risk to patient safety or could affect the public's confidence in pharmacy. This includes:

- concerns about an individual pharmacist or pharmacy technician's fitness to practise
- concerns about an individual's pharmacist or pharmacy technician's registration
- concerns about registered pharmacies
- concerns about the quality of pharmacy education and training, including concerns about an accredited course or an approved pre-registration training placement
- any other potential systemic and/or thematic issues in a registered pharmacy, which could impact on patient safety.

You can find out more about what we investigate on our website at:

- **https://www.pharmacyregulation.org/raising-concerns**
- **https://www.pharmacyregulation.org/raising-concerns-about-pharmacy-education-and-training**

Health and Care Professions Council (HCPC)

The HCPC is an independent regulator set up to protect the public. We regulate 16 health and care professions.

We would like to be informed of any emerging concerns in relation to the following professions:

- Arts therapists
- Biomedical scientists
- Chiropodists / Podiatrists
- Clinical scientists
- Dietitians
- Hearing aid dispensers
- Occupational therapists
- Operating department practitioners
- Orthoptists

- Paramedics
- Physiotherapists
- Practitioner psychologists
- Prosthetists / Orthotists
- Radiographers
- Social workers in England
- Speech and language therapists

Health Education England (HEE)

HEE would like to be informed of emerging or urgent concerns that may present risk of harm to patient or learner safety and need to be shared more quickly than through routine channels. For HEE, learners include both medical and non-medical students, trainees and potentially members of an organisation's staff on an HEE sponsored education and training programme.

Urgent concerns regarding learners, systems and clinical learning environments where learners are trained fall into the following categories:

- Concerns about an individual learner's fitness to practice
- Concerns about the quality of the education, system or environment.

A system concern is about the systems that should be in place to safeguard patients and may include the following issues:

- Inappropriate clinical staffing levels, resources or support
- Confirmed and continued behaviours that undermine professional self esteem
- Management and leadership issues, poor or inadequate clinical supervision
- Equipment and premises
- Persistent or immediate patient safety concerns
- Service reconfiguration plans that would result in risk to fulfilling the requirements of the trainee curriculum.

Local Government and Social Care Ombudsman

The Local Government and Social Care Ombudsman is the final stage for complaints about local authorities, and all adult social care providers (including care homes, and home care agencies). The Ombudsman can investigate all adult social care complaints, including complaints about care that is funded privately without local authority involvement. The Local Government and Social Care Ombudsman works in close partnership with the Parliamentary and Health Service Ombudsman to investigate complaints spanning the health and social care sector.

The Ombudsman has statutory powers to initiate an investigation where it appears a member of the public has, or may have, suffered injustice in consequence of a local authority or care provider's action. The Ombudsman therefore wishes to be informed of any emerging concerns which may warrant an investigation on these grounds.

Additionally, the Ombudsman wishes to be informed of concerns about local authorities or care providers not operating effective complaints systems.

NHS England (NHSE) / Quality Surveillance Groups (QSGs)

The QSGs would like to be informed of relevant emerging concerns about healthcare systems and the healthcare environment relating to NHS-commissioned services.

Information should be shared with the relevant local and/or regional QSG via the central mailbox. The local and/or regional QSG will consider the information alongside other quality data and intelligence as part of the quality assurance process in which providers are subject to routine, enhanced or Risk Summit level of surveillance depending on magnitude of risk. The QSG will also use the information to help inform decisions about whether to call a Single Item QSG or Risk Summit.

Nursing and Midwifery Council

- Any fitness to practise concerns relating to individual nurses/midwives, including those in leadership positions
- Any potential systemic/thematic issues in a health or social care setting which could impact upon the fitness to practise of nurses/midwives
- Any information which suggests a nurse/midwife may still be practising without valid registration
- Any concerns in relation to the standard of education provided by an Approved Education Institution (AEI).

Parliamentary and Health Service Ombudsman (PHSO)

The PHSO is statutorily independent and accountable directly to Parliament. We make final decisions on complaints that have not been resolved by the NHS in England and UK government departments and other public organisations.

Due to our position as the complaint handler of last resort, most of the issues that will be raised via this protocol should be identified before they reach us. We are bound by strict statutory rules about how we can share information before any investigation we conduct has concluded. Before attending any RRP, PHSO will also need to consider the likelihood of the issues being raised coming to us as a future complaint. We will establish and publish our policy on managing such cases. However, we

recognise the importance of multi-agency co-operation to identify serious issues as early as possible to protect patients and their families from the harm that happens when things are allowed to repeatedly go wrong.

10. Recording requirements

Each organisation is expected to record within their own systems. Each organisation should be able to report on:

- Number of times they have initiated the protocol
- Anonymised information about information shared
- RRPs convened
- RRPs attended
- Actions as a result of the protocol

The minimum information expected to be stored is:

- Dates
- Providers, professionals, others involved
- Partners contacted
- Actions agreed and taken
- Decisions to call / not call RRP

11. Sharing personal data

In most uses of the protocol, there should not be a need to share personal data about individuals. Organisations convening an RRP should be aware that if the information they need to share contains personal data, they must ensure that only those who **need** to know the information should attend. Any processing of personal data is subject to the requirements of the General Data Protection Regulation, and each organisation handling personal data must have procedures in place to keep a record of processing activities for personal data. All organisations signing up to this protocol understand that they are responsible for ensuring their organisation's adherence to GDPR, the Data Protection Act and other UK data protection legislation at all times and agree that the provisions set out in Annex C to this

protocol will apply where the organisations which are exchanging personal data under this protocol do not already have a Memorandum of Understanding and/or an Information Sharing Agreement between them.

12. Template regulatory review panel agenda

Convening organisation		Organisation A
Invitees		All partners in the protocol should be considered for invitation, though may decline/not be invited if there is clearly no relevance. Invitees should be aware that if personal data will be discussed then only those partners who need to know this information should attend. Organisation A should advise partners as to whether personal data will be discussed. NB: 'Personal data' is defined under section 1 of the Data Protection Act 1998 available here. Priority should be given to timeliness of the meeting, avoiding excessive delay due to diaries. Organisation A (in conversation with B, C, D) should agree the essential attendees. Attendees should have authority to make decisions about their organisation's ongoing role.
Attendees		Including host organisation
Date and time		As soon as possible after concern raised (within 21 days). Allow 2hrs for meeting
Chair		The most appropriate person from Organisation A
1.	Welcome and introductions	
2.	Briefing from Organisation A	To include: - Summary and origin of emergent concern

		- Presentation of source grading material - Actions taken Where dealing with information received from whistleblowers or other sources who wish to be anonymous/confidential, as they perceive themselves to be e.g. in danger of harassment or violence, we must ensure that their identity is protected. Simple redaction of documents supplied by confidential sources may not protect their identity, so they should not be shared. Careful thought needs to be given by all attendees as to what degree of info as to facts and circumstances about an incident, or setting, can be shared in any discussion/exchange of info, to ensure a confidential source is not (indirectly) identifiable.
3.	Briefing from other agencies involved	To include: - Summary and origin of emergent concern - Presentation of grading material - Actions taken
4.	Review of options for actions	Options include: - Actions from individual organisations - Referral to Quality Surveillance Group as per usual protocols - Contact made with others, such as Controlled Drugs Intelligence Network or Freedom to Speak Up Guardian - Joint actions between organisations - Watching brief - No action needed - If information relates to a Trust in special measures, NHS Improvement should always be informed. NB: The RRP is not a statutory panel with specific legal powers to order or enforce action by individuals or bodies. The RRP is an opportunity for partners to collaborate and discuss how best to use their respective powers.

5.	Decision on next steps	Next steps should always include circulating a redacted summary of the RRP to the emerging concerns working group.
6.	Reflection / evaluation on use of protocol in this instance	

Annex A: Organisations involved

Care Quality Commission (CQC)

CQC's powers are derived from the Health and Social Care Act 2008 and it is responsible for monitoring, inspecting and regulating care services to ensure they meet fundamental standards of quality and safety.

CQC's purpose is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

In all our inspections, we ask five, key questions. Are services:

- Safe?
- Caring?
- Effective?
- Responsive
- Well led?

General Medical Council (GMC)

The GMC is an independent organisation that helps to protect patients and improve medical education and practice across the UK. The GMC's powers and statutory functions are derived from the Medical Act 1983.

- We decide which doctors are qualified to work here and we oversee UK medical education and training.
- We set the standards that doctors need to follow, and make sure that they continue to meet these standards throughout their careers.
- We take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.
- Doctors must be registered with a licence to practise with the GMC, to practise medicine in the UK. We manage the UK medical register.

General Pharmaceutical Council (GPhC)

The GPhC is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales. It is our job to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy.

Our main work includes:

- setting standards for the education and training of pharmacists and pharmacy technicians, and approving and accrediting their qualifications and training

- maintaining a register of pharmacists, pharmacy technicians and pharmacies
- setting the standards that pharmacy professionals have to meet throughout their careers
- investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public
- setting standards for registered pharmacies which require them to provide a safe and effective service to patients
- inspecting registered pharmacies to check if they are meeting our standards.

Health and Care Professions Council (HCPC)

The HCPC is an independent regulator set up to protect the public. We regulate 16 health and care professions. Our key functions are:

- To maintain and publish a Register of health and care professionals who meet HCPC standards for their training, professional skills, behaviour and health.
- To approve education and training programmes within the UK. An individual who successfully completes an approved programme is eligible to apply to the HCPC Register.
- To make sure that someone who has trained outside of the UK has met our standards before we register them.
- To protect the public from those who are not fit to practise. The HCPC will take action against professionals who do not meet these standards or who use a protected title illegally.

Health Education England (HEE)

The Care Act 2014 sets out Health Education England's remit and range of roles and responsibilities in detail. Health Education England (HEE) exists for one reason only: to support the delivery of excellent healthcare and health improvement to the patients and public of England by ensuring that the workforce of today and tomorrow has the right numbers, skills, values and behaviours, at the right time and in the right place.

There are five overarching objectives for HEE:

- Thinking and leading – we will lead thinking on new workforce policy solutions in partnership with the Department of Health and others as appropriate to support high quality and sustainable services;
- Analysing and influencing – we will use high quality data, evidence, advice and workforce expertise to influence the delivery of NHS priorities;

- Changing and improving – we will design and respond positively to innovative recruitment, retention, development and transformation initiatives locally, regionally and nationally which change and improve NHS services and quality of care;
- Delivering and implementing – we will deliver high quality education and training, implement our Mandate and support partner-led programmes to improve the quality of care and services;
- Focusing on tomorrow – we will strategically focus on the future including new roles and pathways to the professions and helping the NHS workforce embrace new technology.

Local Government and Social Care Ombudsman

The Local Government and Social Care Ombudsman is the final stage for complaints about local authorities, and all adult social care providers (including care homes, and home care agencies). The Ombudsman can investigate all adult social care complaints, including complaints about care that is funded privately without local authority involvement. The Local Government and Social Care Ombudsman works in close partnership with the Parliamentary and Health Service Ombudsman to investigate complaints spanning the health and social care sector.

Nursing and Midwifery Council (NMC)

We regulate nurses and midwives in England, Wales, Scotland and Northern Ireland. We exist to protect the public. We set standards of education, training, conduct and performance so that nurses and midwives can deliver high quality healthcare throughout their careers.

We make sure that nurses and midwives keep their skills and knowledge up to date and uphold our professional standards. We have clear and transparent processes to investigate nurses and midwives who fall short of our standards. We maintain a register of nurses and midwives allowed to practise in the UK.

Parliamentary and Health Service Ombudsman (PHSO)

The PHSO makes final decisions on complaints that have not been resolved by the NHS in England and UK government departments and other public organisations. It does this fairly and without taking sides. Its service is free.

Annex B: An example of protocol use

Background

A senior doctor working in the NHS approached a GMC Regional Liaison Adviser (RLA) at a conference and disclosed that they had experienced issues for several months with the quality of surgical equipment used by their organisation.

They stated that the surgical packs were not complete and frequently contained instruments that were poorly assembled and prone to coming apart during surgery. The same supplier provides theatre equipment to other healthcare providers, both public and private. The issue was clearly an urgent patient safety concern and involved doctors, nurses and other healthcare professionals. The organisations' senior management were aware.

This disclosure was clearly about a live and ongoing patient safety concern that went beyond the GMC's statutory functions and was potentially affecting at least three professional groups and a number of NHS and private healthcare organisations. It was determined by GMC senior managers that this information had to be shared urgently with CQC and other partners.

Action taken

- A call between the GMC and CQC took place and agreed that a Regulatory Review Panel (RRP) would be triggered in line with the 'Emerging Concerns Protocol'.
- A redacted intelligence summary was shared with CQC and NMC.
- All of the potential signatories were contacted by CQC.
- Representatives attended a virtual meeting chaired by CQC.
- Delegates were provided with a verbal synopsis of the GMC intelligence.
- Information that CQC had ascertained between the initial call with the GMC and the RRP was shared.
- The NMC updated the call with what they had ascertained from their own data and intelligence.
- CQC confirmed that they were in the process of inspecting the organisation concerned and would seek additional information.
- It was agreed that the Health and Safety Executive (HSE) and Medicines and Healthcare Products Regulatory Agency (MHRA) should be informed.

Impact

- Regulatory action was agreed and taken swiftly by CQC
- Professional regulators shared intelligence and data expeditiously
- HSE and MHRA were briefed within days of the disclosure
- Other signatory organisations were sighted on the issue
- The meeting was over within 45 mins
- Feedback was positive from all attendees.

Annex C: Sharing personal data

In this Protocol, the terms below shall have the following meanings:

‘DPA’	the Data Protection Act 2018 and all other UK data protection legislation
‘FOIA’	the Freedom of Information Act 2000
‘Controller’	has the meaning set out in section 6 of the DPA
‘GDPR’	means Regulation (EU) 2016/679, the General Data Protection Regulation
‘Information Provider’	the Party providing information under the Protocol
‘Information Recipient’	the Party or Parties receiving information under the Protocol
‘Personal Data’	has the meaning set out in section 3(2) of the DPA

Purpose

Personal Data shall only be provided by the Information Provider to the Information Recipient where such Data is relevant to each Information Recipient’s statutory functions, as described in Section 3 of this Protocol (the Purpose).

Any Personal Data shared under this Protocol shall only be used by the Information Recipients for the Purpose and may not be used by the Information Recipient for any other purpose.

The Information Provider may only share Personal Data with the Information Recipient where such sharing complies with the GDPR, the DPA, the Human Rights Act 1998, the common law duty of confidence and all other applicable laws.

Responsibilities of the Parties

The Parties to this Protocol agree that each shall act as an independent Controller for any Personal Data shared under this Protocol.

In respect of any Personal Data shared under this Protocol, each Information Recipient shall:

- ensure that such Personal Data is processed in accordance with the GDPR, the DPA and all other applicable law; and

- comply at all times with the information governance arrangements set out below.

Sharing of information

In all cases where Personal Data is being shared under this Protocol, and in the case of other information where agreed between the Parties, the Information Provider must ensure that the information to be shared is suitably encrypted and/or sent by other secure means.

The Information Provider gives no warranty that the information being shared meets any quality standard or is free from errors.

Nothing in this Protocol shall be interpreted as compelling the Information Provider to disclose any Personal Data to the Information Recipient.

Security

The Information Recipient shall ensure that appropriate technical and organisational measures are taken against unauthorised or unlawful processing of the Personal Data and against accidental loss or destruction of, or damage to, the Personal Data.

The Parties agree to comply with all their own policies on data protection and records management in respect of all information shared under this Protocol.

Personal Data shared under this Protocol shall be retained by the Information Recipient only for so long as is required for the Purpose.

Retention and disposal

At the end of the period specified above, the Information Recipient must securely dispose of all Personal Data provided for the Purpose.

Access to information

The Parties acknowledge that each is subject to the FOIA and that requests for information transferred under this Protocol may be received by any Party under either the FOIA or the DPA. The Parties shall co-operate with each other to ensure that each can comply with their respective obligations under the DPA and the FOIA.

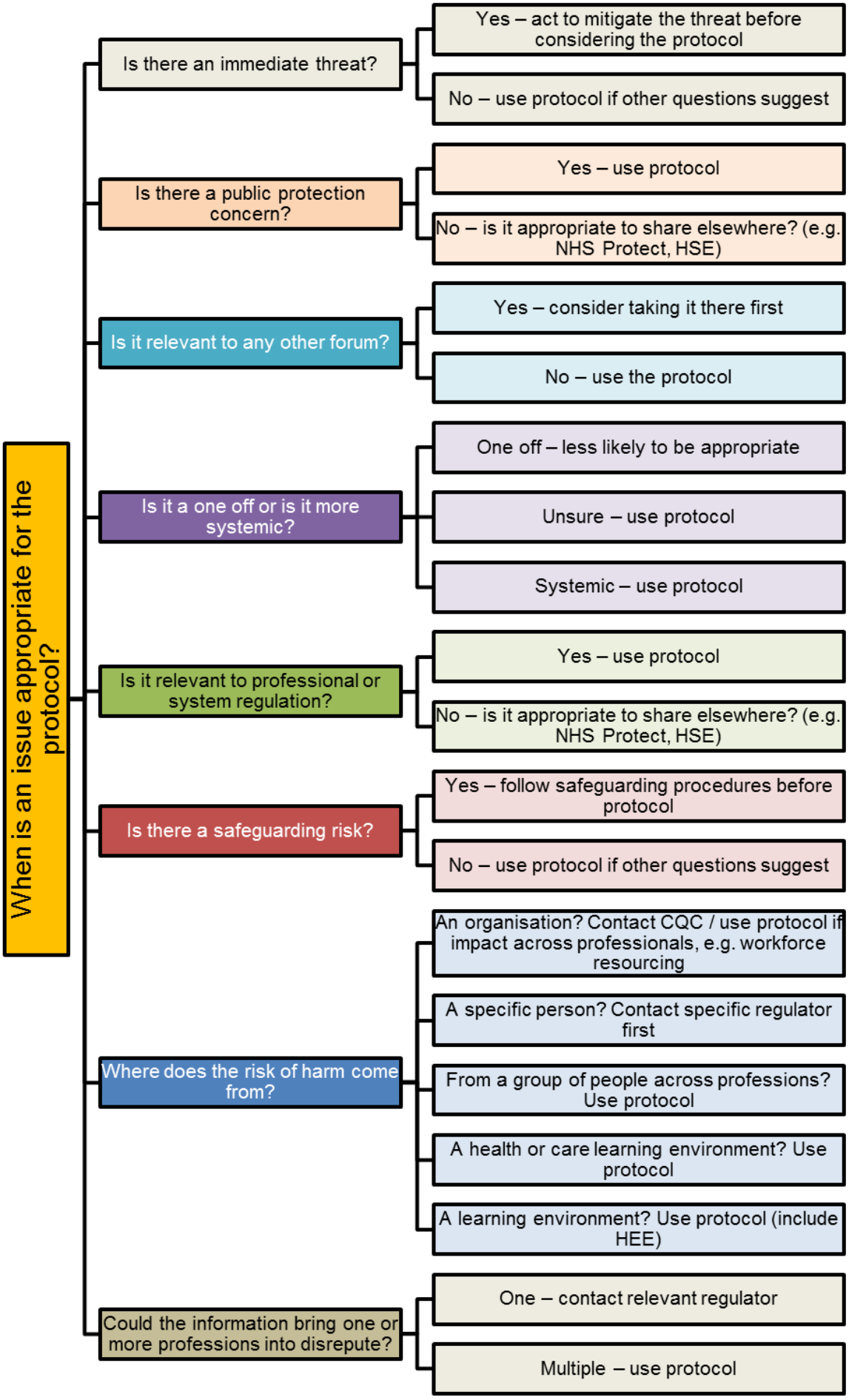
Where the Information Recipient receives a request under either the DPA or FOIA for information that has been provided by the Information Provider, the Information Recipient shall inform the Information Provider promptly of the request.

Confidentiality

All Personal Data and any other information and materials of any Party relating to this Protocol shall not be disclosed to any third party other than a Party's professional advisers or as may be required by law or as may be agreed between the relevant Parties. This clause shall not extend to information which was already in the lawful possession of a Party prior to any meeting of a Regulatory Review Panel under this Protocol or which is already public knowledge or becomes so subsequently (other than as a result of a breach of any duty of confidentiality) or which is required to be disclosed by law. The obligations of confidentiality under this clause shall survive any termination of this Protocol.

Annex D: Questions to consider when determining whether to use the protocol

These questions are intended to support decisions about using the protocol. The questions are not exhaustive, and the answers are intended to give guidance rather than prescriptive direction.


When is an issue appropriate for the protocol?
Is there an immediate threat?
Yes – act to mitigate the threat before considering the protocol
No – use protocol if other questions suggest
Is there a public protection concern?
Yes – use protocol
No – is it appropriate to share elsewhere? (e.g. NHS Protect, HSE)
Is it relevant to any other forum?
Yes – consider taking it there first
No – use the protocol
Is it a one off or is it more systemic?
One off – less likely to be appropriate
Unsure – use protocol
Systemic – use protocol
Is it relevant to professional or system regulation?
Yes – use protocol
No – is it appropriate to share elsewhere? (e.g. NHS Protect, HSE)
Is there a safeguarding risk?
Yes – follow safeguarding procedures before protocol
No – use protocol if other questions suggest
Where does the risk of harm come from?
An organisation? Contact CQC / use protocol if impact across professionals, e.g. workforce resourcing
A specific person? Contact specific regulator first
From a group of people across professions? Use protocol
A health or care learning environment? Use protocol
A learning environment? Use protocol (include HEE)
Could the information bring one or more professions into disrepute?
One – contact relevant regulator
Multiple – use protocol
Are you unable to answer, or is there still a residual concern? If so, use protocol