

# NATIONAL PATIENT SAFETY AGENCY

## Assuring patient safety through risk assessment

### A guide to assist commissioners of out-of-hours services

#### Introduction

The National Patient Safety Agency (NPSA) has developed a guide to support commissioning for patient safety in out-of-hours (OOH) services.

This guide is to help commissioners ensure that patient safety is appropriately considered by new and existing OOH service providers during service development, service reviews and during quality review and monitoring.

Commissioners of OOH services should expect providers to be able to demonstrate that they have focussed on patient safety by undertaking comprehensive patient safety risk assessments.

#### Commissioning for Patient Safety

Commissioning for Patient Safety is when risk assessment methodologies are used to focus on patient safety during the process of service planning, design and implementation.

Commissioners need to be assured that the OOH services they commission are safe for patients as well as providing efficient, effective and high quality care. Risk assessments carefully examine systems to identify factors that could potentially cause or contribute to patient harm. They highlight whether adequate precautions are being taken to ensure timely and safer provision of care, or if further measures are needed to prevent harm.

The process of risk assessment seeks answers to four simple, related questions.



Risk assessments can vary depending on the risk assessment tool(s) used. Illustrations of risk assessments using case studies from patient pathways are presented in an appendix. There are, however, key components to effective risk assessments that commissioners should expect OOH service providers to demonstrate:-

1. That there is detailed understanding of the service to be provided. For example, have the following issues been considered:
  - How have patients' needs and experiences been considered?
  - Have appropriate supporting data sources been used?
  - What are the workforce capacity and capability requirements, how have they been determined and how will they be met?
  - What infrastructure is available?
  - What integrated service modelling has been utilised?
  - How have care professionals contributed to the process?
2. Evidence that the service has been comprehensively mapped, that is breaking the service down into its component parts.
3. Evidence that the service providers have identified all the things that could go wrong and compromise patient safety, both the likely and less likely events – using 'What If' questions.
4. Evidence that the service providers have considered and documented the likely causes and consequences of what could go wrong and identified failures.
5. Evidence that a risk matrix has been used to assess the frequency, likelihood and impact of the identified failures.
6. Evidence that targeted recommendations and implementation strategies that reduce the risks (and do not introduce new risks) have been developed.

Commissioners of OOH services should seek evidence that providers have considered patient safety throughout the development and implementation of a new OOH service and as part of ongoing quality review and monitoring of existing services.

When to undertake a risk assessment	New OOH service	Existing OOH service
Initial stages of OOH service development	To highlight if the basic model/design provides appropriately safe care	
Detailed OOH systems design	To highlight if <u>each</u> patient pathway provides safe care	As part of a review of the service
Service modification	To ensure that any modified patient pathway provides as safe care as possible	To ensure that any modified patient pathway provides as safe care as possible
Quality review and monitoring	Post-implementation – to ensure that new risks have not been unintentionally introduced	To ensure that new risks have not been unintentionally introduced

## **Resources**

- NPSA, 2005, Seven steps to patient safety for primary care. The full reference guide. London, UK: NPSA. [www.npsa.nhs.uk/sevenstepsforprimarycare](http://www.npsa.nhs.uk/sevenstepsforprimarycare)
- OOHs Standards – DH 2004 National Quality Requirements in the Delivery of Out-of-hours Services

## **Acknowledgements**

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Croydoc	Wirral Emergency OOH Service
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Nottingham Emergency Medical Services	Harmoni cpo
Rushcliffe PCT	Trent Strategic Health Authority
Leicestershire, Northamptonshire and Rutland Strategic Health Authority	
Essex Ambulance Service NHS Trust	

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## **Further patient safety risk assessment support**

If you would like further assistance with risk assessing a service or patient pathway, contact your local NPSA patient safety manager (see [www.npsa.nhs.uk/static/contacts](http://www.npsa.nhs.uk/static/contacts) ). Further information on how to undertake a risk assessment will be available on the NPSA website from May 2006 at [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

## **Feedback**

We would appreciate your feedback on this document and/or the proposed approach. Please send your comments to:

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[www.npsa.nhs.uk](http://www.npsa.nhs.uk)

Or email [enquiries@npsa.nhs.uk](mailto:enquiries@npsa.nhs.uk), marked for the attention of the Head of Safer Practice (primary care).

## **APPENDIX**

### **Case Study 1: Palliative Care**

It is often only when out-of-hours (OOH) service systems fail that healthcare organisations investigate how and why such events occur. The palliative care case study presented in Box 1 outlines the palliative care patient safety failings of an OOH service. However, to improve patient safety in OOH patient pathways then a proactive risk assessment of the system needs to be undertaken to help identify risk areas and investigate recommendations that improve patient safety.

#### **Box 1: Palliative care in out-of-hours**

Emily was diagnosed with a brain tumour in August 2002 when she was 24 years old. She was a chiropodist. She was fit and active and managed her medication herself for many weeks, apart from when she had severe relapse symptoms when a syringe driver needed to be set up. This happened on three occasions between September 2002 and February 2003; during these times she was entirely dependant on her parents.

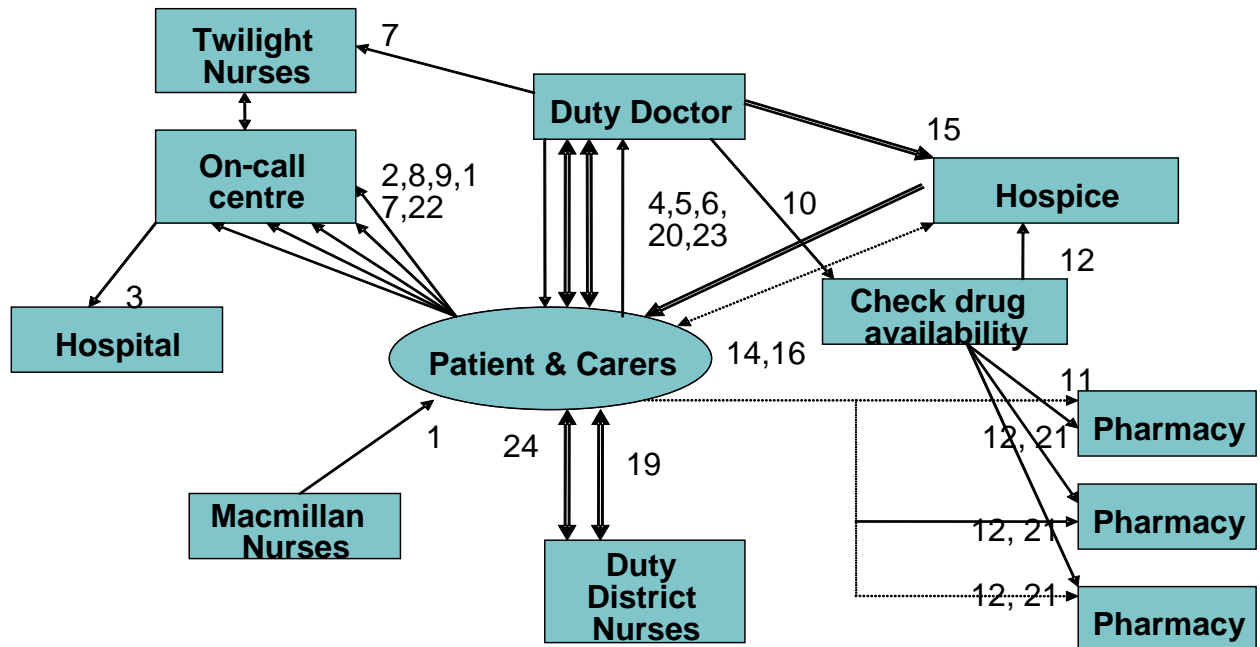
#### **The sequence of events**

**Friday Afternoon** – syringe driver set up by district nurses attached to Emily's GP practice.

1. **Saturday morning** – Dose of analgesia increased; dexamethasone started as per chart by Macmillan Nurses.
2. **Saturday midday** – Emily's condition worsened, on-call centre phoned. No record of Emily or her condition, and no notes available.
3. On-call centre phoned hospital ward for more information but only "skeleton" staff on duty and no information available.
4. On-call duty doctor visited. Emily had settled a little and no action was taken. The doctor asked for a report at 6pm.
5. **Saturday 2pm** – Emily becomes very distressed and the doctor was contacted again. **Saturday 6pm** – The doctor visits and gives an injection of midazolam and leaves a prescription for one vial (prescription unused). No information given to parents about Emily's condition. No repeat visit or follow up arranged. Doctor said a message would be left with twilight nurses.
6. **Saturday 10pm** – Emily's condition deteriorated again and she was in much distress. On-call centre phoned – parents asked to phone back as doctor's were changing shift.
7. Parents call on-call centre again. Decision taken that more midazolam needed.
8. **Saturday Midnight** – New on-call doctor still trying to locate midazolam. Some found at a local hospice.
9. Father was asked to drive there to collect supply. Was left alone in a dark corridor where he could hear staff discussing Emily. After 30 minutes, was told he was not authorised to carry the drug.
10. Father returned home. Emily still very distressed.
11. **Sunday 1am** – doctor arrives with drugs.
12. **Sunday 2am** – Emily settled.
13. **Sunday 10am** – Parents planned for needing more midazolam over Sunday into Monday morning. They phoned the on-call centre and the doctor arranged a prescription.
14. Parents drove to collect the prescription
15. They also contacted several pharmacies to make sure that they were open and had stocks available (no one had sufficient to fulfil whole prescription).
16. Back in time for the week-end duty district nurses to administer an injection and recharge the syringe driver. Emily now needed more pain relief. Nurses reluctant to increase dose without authorisation and want to wait to see how she is in the morning. **Sunday midday** – Nurses left.

18. Parents phoned on call doctor who wrote prescription for increased pain relief dose.
19. Parents drove to collect the prescription and then to a different pharmacy to collect medicine. (Full amount not available).
20. Father returned home and telephoned on-call centre for someone to administer pain relief.
21. **Sunday 2pm** – duty doctor and district nurse returned to administer increased dose of pain relief. Emily remained comfortable from this time until Monday morning when her GP practice resumed care.

**Number and type of interactions during OOH for palliative care**



Number of interactions

One patient in 36 hours had 24 contacts with 7 healthcare agencies.

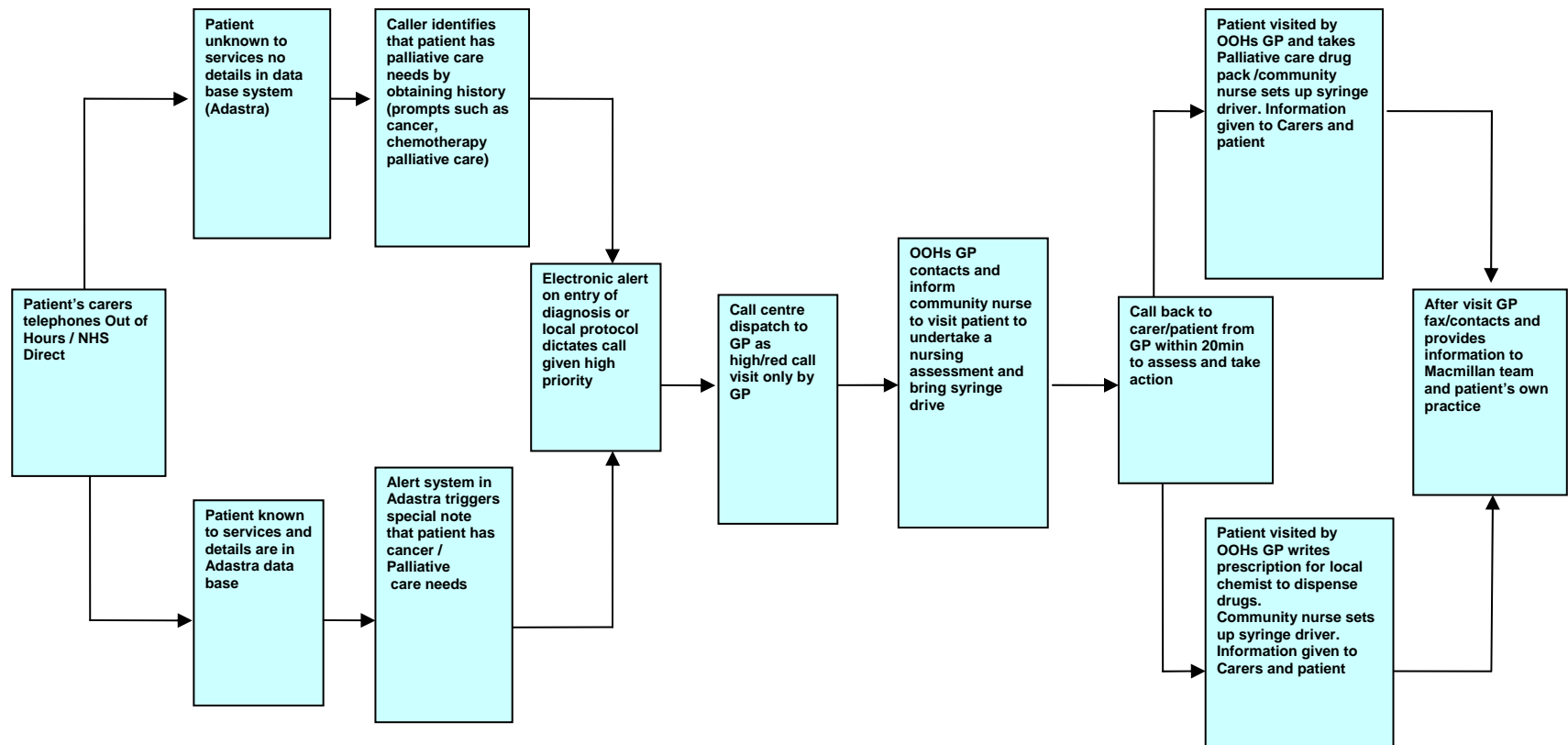
Issues

- Complexity of the system
- Large number of interactions
- No single locus of clinical responsibility
- Communication problems

### Fundamental components of risk assessment

A pro-active risk assessment could have identified the issues (risks). Risk assessments will vary depending on the OOH service to be provided and the specific risk assessment tool(s) that have been used. However, there are four key components to an effective risk assessment that commissioners should expect to see in any risk assessment document; a detailed understanding of the patient pathway; comprehensive mapping of the pathway; use of “What If?” questions; and completion of a risk assessment record.

**Figure 1: An example of mapping part of the palliative care OOHs service delivery process**



A small team uses the process map as a systematic prompt to consider all the things that could go wrong by using a series of 'What If' questions. Table 1 provides an example of a generic and specific palliative care 'What If' Question set.

**Table 1: 'What If' generic set of questions and specific 'What If' for palliative care**

<b>Generic prompt questions</b>		
<b>Prompt</b>	<b>Generic 'What If' questions</b>	<b>Specific example of 'What If' questions</b>
Omits entire activity	What if the activity does not take place?	What if call handler fails to recognise that the patient has palliative care needs?
Omits activity step	What if only part of the activity takes place?	What if OOHs GP visits the patients without the palliative care drug pack?
Action at wrong time (too early/too late)	What if the activity takes place too early?	What if OOHs GP arrives with drugs before community nurses arrive with Syringe driver?
Action incorrectly performed	What if the activity is delayed?	What if palliative care drug pack is not restocked or the local chemist has no stock of the prescribed drug?
Selection errors	What if too much activity takes place?	What if OOHs GP informs Macmillan team and community nurses and they all arrive at the patient's home around the same time?
Sequence errors	What if the activity takes too long?	What if there is a delay in visiting due to delay in OOHs GP calling back patient for further assessment?
Omits entire activity	What if the activity is too short?	What if community nurse had limited time with patient due to other workload and in a rush to set up a syringe driver?
Omits activity step	What if the activity is repeated?	What if patient's own GP was unaware of OOH visit?
Action at wrong time (too early/too late)	What if right activity on wrong object?	What if care pathway is not followed?
Action incorrectly performed	What if wrong activity on right object?	What if the care pathway is not followed?
Selection errors	What if wrong information obtained / transmitted?	What if the operator at the call centre fails to collect patient details correctly?
Sequence errors	What if incorrect sequence?	What if the pathway is not followed in order?

**Table 2: An example of a completed risk assessment record for mapped part of the palliative care service delivery process for patients.**

ID (1)	What could go wrong? (2)	Cause (why) (3)	Consequences (4)	Current controls (5)	Risk ranking			Recommendations (9)	Risk ranking		
					C (6)	L (7)	R (8)		C (10)	L (11)	R (12)
1	Palliative care drug pack is not restocked or the local chemist has no stock of the prescribed drug.	<ol style="list-style-type: none"> <li>Clinician failed to get the palliative care drug pack restocked.</li> <li>Local pharmacy not informed about having patients locally with palliative care needs such as symptom relief.</li> <li>Local pharmacy failed to re-order new stock.</li> </ol>	<ol style="list-style-type: none"> <li>Delay in treatment of symptoms.</li> <li>Patient left in extreme distress and discomfort.</li> </ol>	<ol style="list-style-type: none"> <li>Protocols and pathways of care/clinical handbook.</li> <li>Chemist has stock check system.</li> <li>Training.</li> </ol>	H	M	M	<ol style="list-style-type: none"> <li>Have a system where once the palliative care pack is open it cannot be closed thus not returned empty.</li> <li>Service level agreement with PCT and community pharmacy.</li> <li>Good communication with the transfer of care from hospital/out patients to community care package to be arranged on transfer/discharge.</li> <li>Good communication with in-hours GP and OOHs regarding treatment and assessment.</li> <li>Proactive risk assessment to anticipate patient</li> </ol>	M	L	M

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2	Call handler fails to identify patient has palliative care needs.	<ol style="list-style-type: none"> <li>1. Carer or patient poor historian.</li> <li>2. Call handler not familiar with prompts or alert system.</li> <li>3. Call handler/caller has problems with communication.</li> <li>4. Electronic alert system not in place.</li> </ol>	<ol style="list-style-type: none"> <li>1. Patient may not be assessed by GP.</li> <li>2. Delay in assessment and treatment of symptoms.</li> <li>3. Patient left in extreme distress and discomfort.</li> </ol>	<ol style="list-style-type: none"> <li>1. Training.</li> <li>2. Protocol and care pathway.</li> <li>3. Verbal communication for alerting receiving clinician.</li> <li>4. Alert system in place on Adastra/special note or colour codes.</li> </ol>	H	M	M	<p>needs for the next 48 hours especially weekend with regards to medication and symptom control, prescription and drugs kept at patients home.</p> <ol style="list-style-type: none"> <li>1. Electronic systems to be installed to trigger an alert that the patient has palliative care needs.</li> <li>2. Good communication with the transfer of care from hospital/out patients to community.</li> <li>3. Care package to be arrange on transfer with anticipated prescription.</li> </ol>	M	L	M
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Rank risks by using a risk matrix: C = Consequence, L = Likelihood, R = Risk, H = High, M = Medium and L = Low

## **Case Study 2: Abnormal Laboratory Results**

### **Box 2: Abnormal laboratory results in out-of-hours**

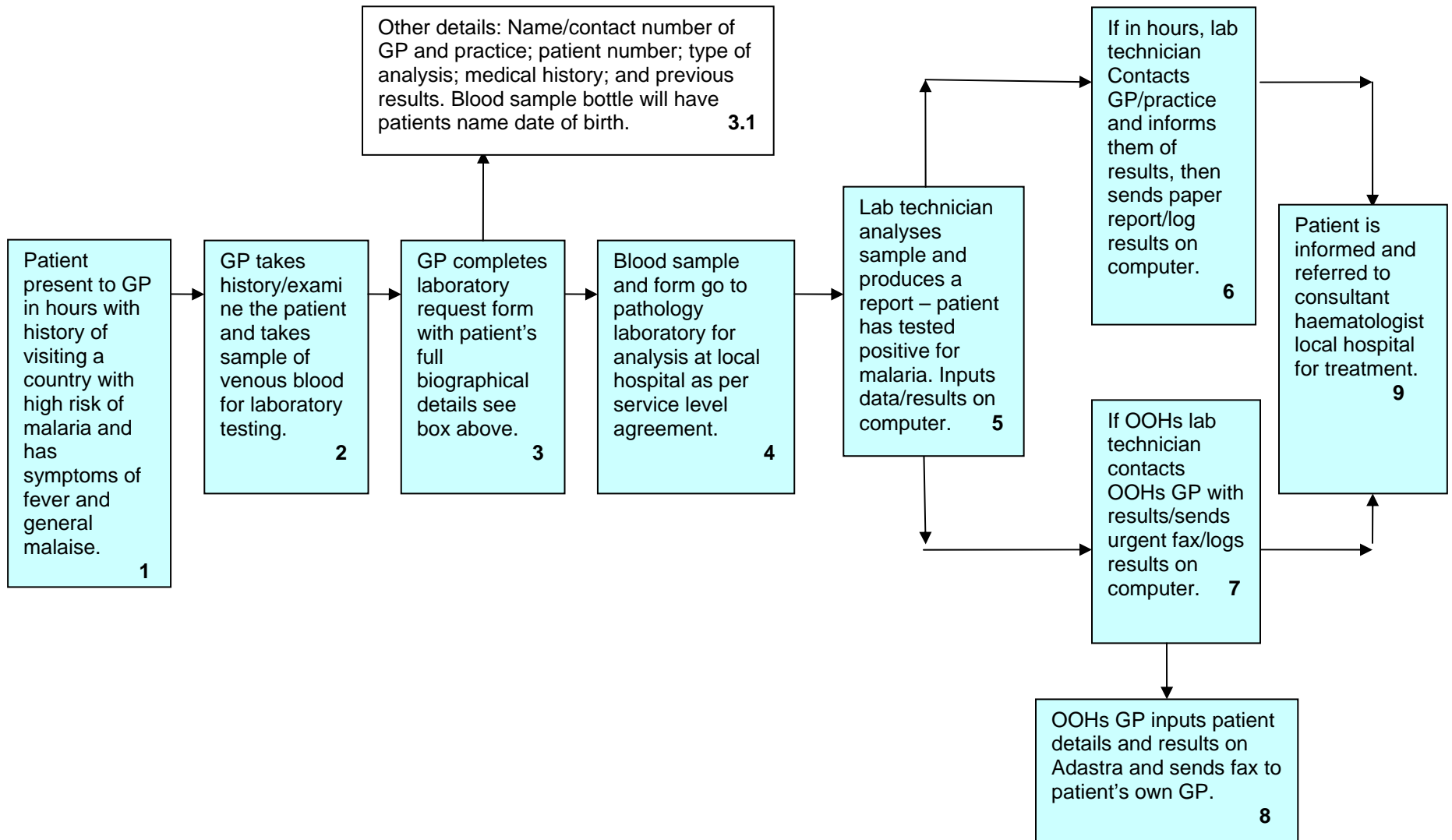
On Friday 20 January 2006, Mr K went to visit a GP at his practice with signs and symptoms of fever and general malaise. He had also recently visited a country which was considered high risk with regards to malaria.

Given this, the GP did an assessment and a haematology test for the patient. The specimen was logged in at the specimen reception at 5:30pm.

The consultant haematologist was notified of the result at 7pm as positive for malaria. In line with the hospital's policy and the Royal College of Pathologists out of hours reporting advice, the lab technician had already tried to pass on the results to the GP. The GP surgery was closed and the technician had spoken to the locum agency covering for the GP. The agency advised that they could not take the results of the test as the lab technician did not have the patient's complete details including their address and/or telephone number. No NHS number had been entered on the request form. The patient had not been seen at Hospital X previously and therefore was not on the PAS system. The agency did not have access to the GP's list of patients.

The consultant haematologist phoned the agency and asked to speak to the manager, who accepted the patient's details reluctantly. A paper copy of the result was sent to the GP the following week (Mon/Tues). The outcome for the patient is unknown.

**Figure 2: An example of mapping part of the abnormal lab results service delivery process**



Once a detailed understanding of the service has been generated the service to be provided can be comprehensively mapped. A small team then uses the process map as a systematic prompt to consider all the things that could go wrong by using a series of 'What If' questions. Table 3 provides an example of a specific abnormal laboratory results 'What If' set of questions.

**Table 3: Specific 'What If' set of questions for abnormal laboratory results**

Prompt questions		Example of 'What If' questions
Prompt	Hazard 'What If' questions	Activity: Communicating abnormal lab test results OOH
Omits entire activity	What if the activity does not take place?	<ul style="list-style-type: none"> <li>What if the venous blood sample has been taken and left at the GP practice?</li> </ul>
Omits activity step	Part of the activity takes place?	<ul style="list-style-type: none"> <li>What if a venous blood sample was taken but patient's biographical details have been recorded incorrectly or omitted; for example their address/identification number?</li> </ul>
Action at wrong time (too early/too late)	What if activity takes place too early or is delayed?	<ul style="list-style-type: none"> <li>What if a venous blood sample was taken but patient's biographical details were recorded incorrectly or omitted? OOHs agency reluctant to receive results because of insufficient details and patient is not diagnosed until results via lab report have been received by GP one week later.</li> </ul>
Action incorrectly performed	What if too much activity takes place?	<ul style="list-style-type: none"> <li>What if venous blood samples were taken investigation from different patients presenting with varying problems and their biographical details were incorrect or missing?</li> </ul>
Selection errors	What if right activity on wrong object?	<ul style="list-style-type: none"> <li>What if wrong information was written on laboratory request form regarding the right patient? In other words right patient wrong details.</li> </ul>
Sequence errors	What if incorrect sequence?	<ul style="list-style-type: none"> <li>What if lab results not communicated to medical office immediately?</li> </ul>

**Table 4: Provides an example of a completed risk assessment record for part of the abnormal laboratory results service delivery process for patients.**

ID (1)	What could go wrong? (2)	Cause (why) (3)	Consequences (4)	Current controls (5)	Risk ranking			Recommendations (9)	Risk ranking		
					C (6)	L (7)	R (8)		C (10)	L (11)	R (12)
3	A venous blood sample was taken but patient's biographical details were recorded incorrectly or omitted for example address/NHS number.	<ol style="list-style-type: none"> <li>The clinician omits certain details because of a lapse or lack of time.</li> <li>The clinician omits certain details because he is not aware of the importance of obtaining certain information.</li> </ol>	<ol style="list-style-type: none"> <li>Delay in diagnosis.</li> <li>Risk of condition worsening.</li> <li>Risk to others within the community.</li> </ol>	<ol style="list-style-type: none"> <li>Procotols and pathways of care/clinical handbook.</li> <li>Computerises records.</li> <li>Training.</li> </ol>	H	H	H	<ol style="list-style-type: none"> <li>Raise awareness of the importance of completing pathology request forms correctly.</li> <li>Reactive learning and risk assessment to anticipate the risk of this happening again and to look at what controls to put in place locally.</li> <li>Receptionist to do a final check for missing information before sample is sent to path lab.</li> </ol>	M	M	M
3	A venous blood sample was taken but patient's biographical details were recorded incorrectly or omitted. OOHs agency reluctant to receive results because of insufficient details.	<ol style="list-style-type: none"> <li>The clinician omits certain details because of a lapse or lack of time.</li> </ol>	<ol style="list-style-type: none"> <li>Delay in diagnosis.</li> <li>Risk of condition worsening.</li> <li>Risk to others within the community.</li> </ol>	<ol style="list-style-type: none"> <li>Protocol and care pathway.</li> <li>Computerises records.</li> <li>Training.</li> </ol>	H	H	H	<ol style="list-style-type: none"> <li>Raise awareness of the importance of completing pathology request forms correctly</li> </ol>	M	M	M

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ID (1)	What could go wrong? (2)	Cause (why) (3)	Consequences (4)	Current controls (5)	Risk ranking			Recommendations (9)	Risk ranking		
					C (6)	L (7)	R (8)		C (10)	L (11)	R (12)
		2. The clinician omits certain details because not aware of the importance of obtaining certain information.						2. Incident investigation where OOHs / Lab team and PCT get together to discuss and learn form incident. A risk assessment to anticipate the risk of this happening again and to look at what controls to put in place locally.  4. Receptionist to do a final check for missing information before sample is sent to path lab.			

Rank risks by using a risk matrix: C = Consequence, L = Likelihood, R = Risk, H = High, M = Medium and L = Low

### **Case Study 3: Study of a patient receiving Warfarin**

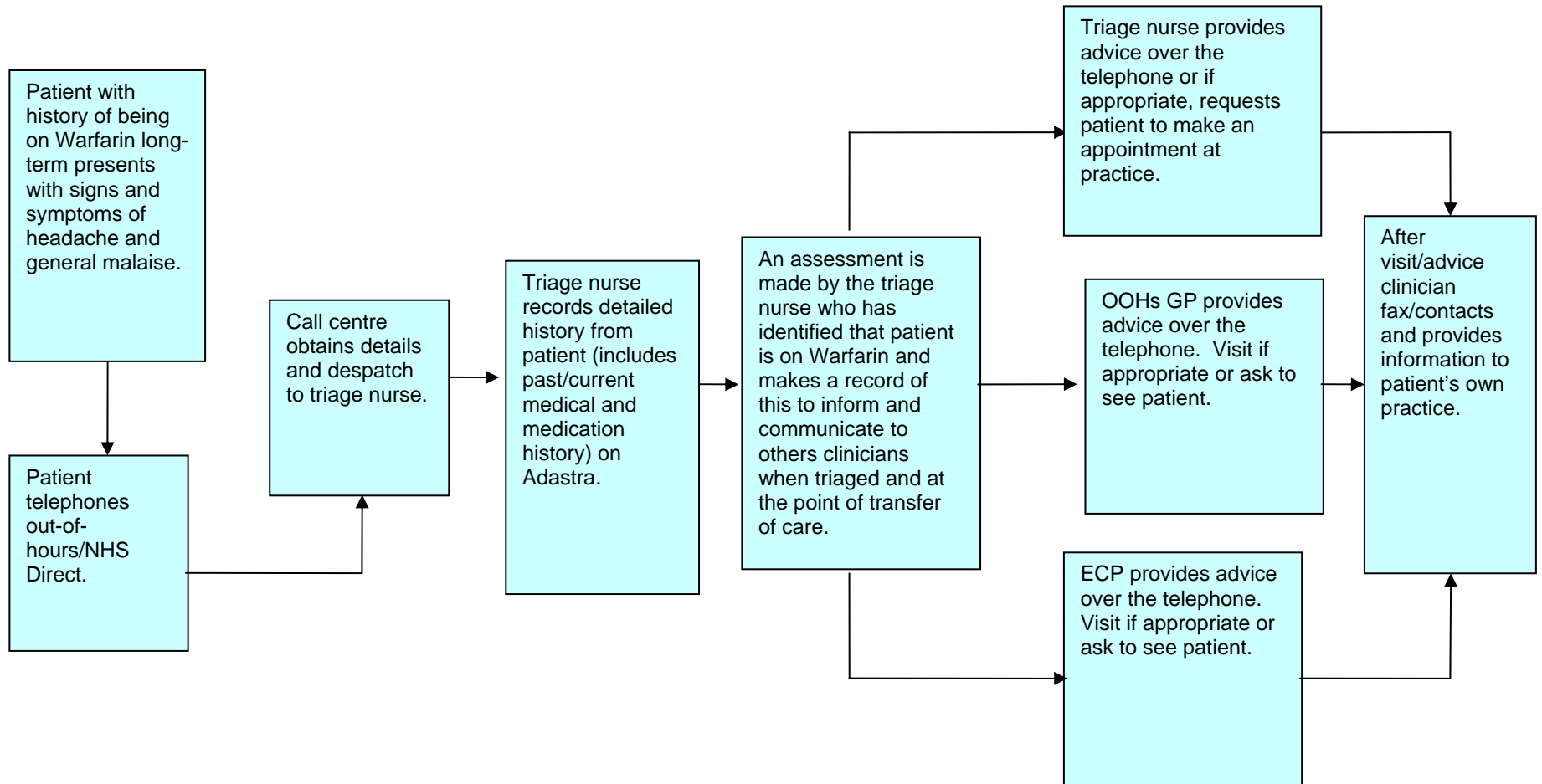
#### **Box 3: Out-of-hours care of a patient taking Warfarin**

On Friday 13 January 2006, Mrs X went to visit her GP because of she was feeling unwell with persistent headaches and general malaise. She is well known to the practice and GP since she has been taking Warfarin for many years for her multiple transient ischaemic attacks. Her GP assessed her and suggested that she had sinusitis and advised paracetamol, steam inhalations and rest.

On the Saturday morning Mrs X signs and symptoms got increasingly worse and she felt very unwell indeed. After sometime and with persistent encouragement from her friend she decided to make a telephone call to OOHs .The call centre referred her call to the triage nurse who took more details, made an assessment and decided to continue with the diagnosis of sinusitis and gave telephone advice to continue with paracetamol, steam inhalations and rest. At this point of history taking the triage nurse did write in the notes that Mrs X was on Warfarin.

A few hours passed and Mrs X's condition was worsening and her friend insisted that she contact OOHs again and insist on a visit. This was carried out and at 2pm the emergency care practitioner (ECP) went to visit Mrs X at her home. The ECP made another assessment and he too made a record that Mrs X was on Warfarin but still continued to follow the GPs diagnosis of sinusitis and recommended the same regime. At this point Mrs X's friend was outraged and insisted that she needed hospital attention. The ECP referred her to the local acute trust. Mrs X was admitted on a surgical ward with a diagnosis of a sub-dural haematoma and subsequently transferred to a neurosurgical unit.

**Figure 3: An Example of mapping part of the Warfarin case service delivery process**



Once a detailed understanding of the service has been generated the service to be provided can be comprehensively mapped. A small team then uses the process map as a systematic prompt to consider all the things that could go wrong by using a series of 'What If' questions. Table 4 provides an example of a specific Warfarin 'What If' set of questions.

**Table 4: 'What If' Generic set of questions and specific 'What If' for Warfarin case**

Prompt questions		Example of 'What If' questions
Prompt	Hazard 'What If' questions	Activity: Failure to recognise that patient is on anticoagulant – Warfarin
Omits entire activity	What if the activity does not take place?	<ul style="list-style-type: none"> <li>What if the assessing practitioner fails to obtain a detailed past medical history and fails to establish that the patient has been taking Warfarin for many years?</li> </ul>
Omits activity step	What if only part of the activity takes place?	<ul style="list-style-type: none"> <li>What if assessing practitioner fails to transfer vital information such as the patient has been taking therapeutic anticoagulants such as Warfarin?</li> </ul>
Action at wrong time (too early/too late)	What if the activity takes place to early the activity is delayed?	<ul style="list-style-type: none"> <li>What if the assessing practitioner obtains detail medical history but the patient fails to inform the practitioner about their medication history but tells another practitioner at a later time?</li> </ul>
Action incorrectly performed	What if too much activity takes place?	<ul style="list-style-type: none"> <li>What if the OOHs GP is distracted by an emergency call out and forgets to recall that the patient is on Warfarin?</li> </ul>
Selection errors	What if right activity on wrong object?	<ul style="list-style-type: none"> <li>Did not follow pathway.</li> </ul>
Sequence errors	What if incorrect sequence?	<ul style="list-style-type: none"> <li>Did not follow pathway.</li> </ul>

**Table5: Provides an example of a completed risk assessment record for part of the Warfarin Case service delivery process for patients.**

ID (1)	What could go wrong? (2)	Cause (why) (3)	Consequences (4)	Current controls (5)	Risk ranking			Recommendations (9)	Risk ranking		
					C (6)	L (7)	R (8)		C (10)	L (11)	R (12)
1	The assessing clinician/practitioner fails to establish that the patient has been taking Warfarin for many years.	1. Clinician / practitioner failed to take adequate medical and medication history.  2. No checklist in place.	1. Delay in treatment.  2. Patient at risk of severe haemorrhage or other contra-indications.	1. Protocols and pathways of care/clinical handbook.  2. Training.  3. INR results.	H	M	M	1. Reactive learning and risk assessment to anticipate the risk of this happening again and to look at what controls to put in place locally.  2. Systems in place such as checklist for the assessing clinician / practitioner to go through at the end of the assessment.  3. Further training on the significance of obtaining correct medication history and their contraindications.  4. Encourage patients to be involved in their care. GPs to inform their patients the important of informing other healthcare professionals that they are taking anticoagulants	M	L	M

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ID (1)	What could go wrong? (2)	Cause (why) (3)	Consequences (4)	Current controls (5)	Risk ranking			Recommendations (9)	Risk ranking		
					C (6)	L (7)	R (8)		C (10)	L (11)	R (12)
2	The practitioner / clinician identifies that the patient is on Warfarin but fails to recognise the significance of this.	<ol style="list-style-type: none"> <li>1. Clinician / practitioner have no awareness.</li> <li>2. Clinician / practitioner continue with initial assessment and fail to associate symptoms with the side affects of the medication.</li> </ol>	<ol style="list-style-type: none"> <li>1. Delay in treatment</li> <li>2. Patient at risk of irreversible neurological damage/severe haemorrhage or contra-indications.</li> <li>3. Misdiagnosis.</li> </ol>	<ol style="list-style-type: none"> <li>1. Training.</li> <li>2. Protocol and care pathway.</li> <li>3. INR Results.</li> </ol>	H	M	M	<ol style="list-style-type: none"> <li>1. Reactive learning and risk assessment to anticipate the risk of this happening again and to look at what controls to put in place locally.</li> <li>2. To look at the possibility of having a system that triggers an alert for specific drugs to raise an alarm for assessing clinician/ practitioner.</li> <li>3. Further training on the significance of obtaining correct medication history and their contraindications.</li> </ol>	M	L	M

Rank risks by using a risk matrix: C = Consequence, L = Likelihood, R = Risk, H = High, M = Medium and L = Low