Targeted Process Methodology

'A Proportionate Response to Training Quality Concerns'

Context:

Heath Education and Improvement Wales, (HEIW) is accountable to the GMC/GDC as the regulator for the quality of postgraduate medical and dental education and training in Wales. This responsibility is discharged through the application of HEIW's Quality Management Framework which has been implemented to ensure that training and education meets national standards.

The Targeted Process is the responsive component of HEIW's Quality Management Framework and provides a mechanism for the HEIW to quality manage concerns pertaining to the quality of education and training as and when they arise, as opposed to confining action to routine processes which inevitably has the potential to adversely impact patient or trainee safety. The process is evidence based and has been specifically designed to ensure that a proportionate response to concerns is adopted.

The Targeted Process is closely related to the Quality Unit's Risk Process which ensures transparency with local education providers and training programme leads around the type and severity of quality concerns being managed. This risk based approach also maximises the opportunities for local quality control enabling issues to be addressed at an early stage. Given that the HEIW is ultimately accountable to the relevant regulator for the quality of postgraduate medical and dental education the process also has a clear link with regulatory processes and this is outlined in the detail of the methodology, a visual representation of which can be seen in figure 2, 'Targeted Process Overview'.

In addition to having responsibility to the relevant regulator of postgraduate medical and dental education, HEIW also has explicit links with other regulators which are maintained through the following mechanisms:

- The Wales Concordat which was established to provide a platform for collaboration between audit, inspection, regulation and improvement bodies.

- HEIW has an explicit Memorandum of Understanding with Healthcare Inspectorate Wales, (HIW) which provides a framework around the working relationship between the two organisations. Given HIW's role as the service regulator the primary purpose of this relationship is to promote patient safety through sharing intelligence appropriately.

Process Scope

The scope of this process is confined to the management of concerns regarding the quality of postgraduate medical and dental education and training in line with regulatory standards. This process document is intended to be used or referred to by individuals who have an active role in the

management of concerns pertaining to the quality of postgraduate medical and dental education. Complimentary documentation is available outlining how to raise concerns together with a brief summary for those wishing to gain an overview of the process is available from HEIW's Quality Unit.

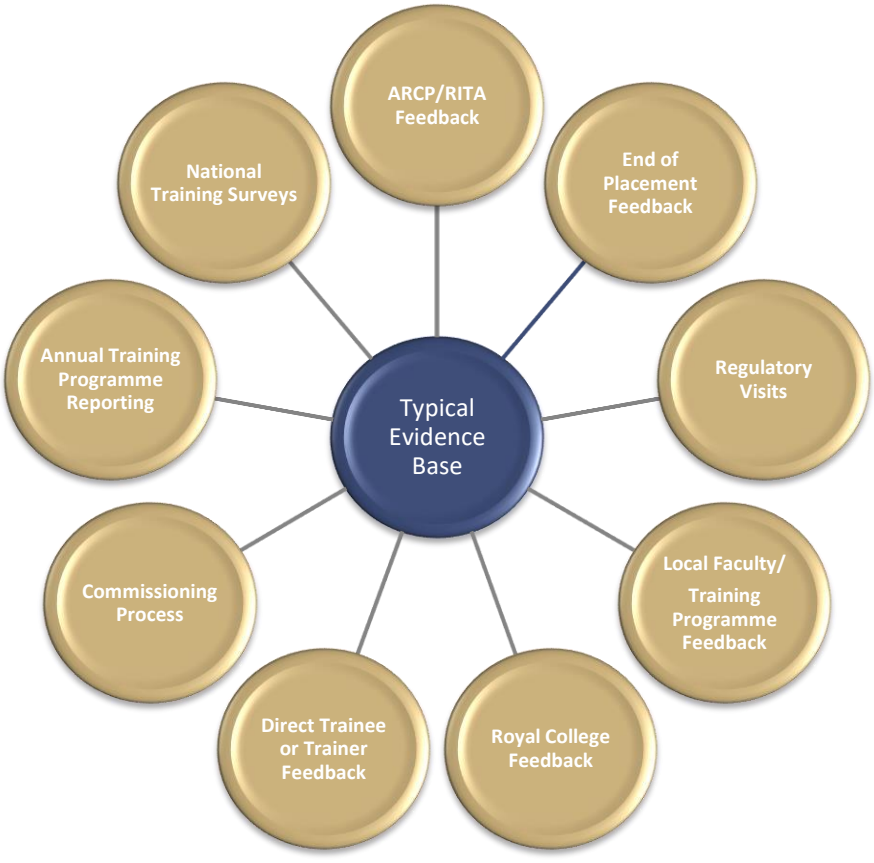
Methodology

The Targeted Process achieves the aim of ensuring a proportionate response to concerns through adopting a staged approach to the management of training issues. There are four stages within the process the details of which are provided within the following paragraphs. Whilst concerns frequently escalate and de-escalate through the various stages of the process, it is not always necessary for this to be undertaken sequentially. The stage at which a concern is managed will be based upon the risk rating which is derived from considering the nature of the concern and the associated evidence base. This ensures that the HEIW is responsive to the severity of the concern thereby putting patient safety at the core of the process. At all stages communication should include both local faculty and training programme structures to ensure that all available evidence is considered and to prevent parallel action planning processes.

Evidence Management:

Concerns pertaining to the quality of postgraduate medical and dental education and training may be identified through a variety of sources. The radial diagram in figure 1 below provides details of the typical sources of evidence that are utilised to identify training concerns. Whilst the evidence sources in the diagram represent the typical evidence base it is important to note that the Quality Unit within HEIW will consider all available sources of evidence in the management of training concerns.

Figure 1: Typical Evidence Sources



Stage I: Initial Enquiry

A Stage I 'Enquiry' is appropriate where a concern has been identified but the evidence presented is not triangulated. In such circumstances there is a need to initiate an initial enquiry which may originate from a range of sources including the trainees, trainers, local faculty, training programme structures, external stakeholders or regulatory processes. The primary aim of this stage is to establish whether or not a concern can be substantiated based upon the evidence and if so to take action to resolve the issue at the earliest opportunity. This would typically involve obtaining further information on the nature of the concern and any contextual information which may have contributed towards the concern being raised. In addition, details of any action which may have already been undertaken in order to resolve the issue in a prompt manner would also be sought.

Stage 1 may also be applied where a concern from a higher stage in the process has de-escalated and monitoring is required for a period of time prior to closure to ensure that improvements are sustained.

Potential Stage Outcomes:

The conclusion of an enquiry will result in one of the following three possible outcomes:

1. That no further action is necessary in which case details of the initial concern and findings should be logged with the Quality Unit and the case will be closed. However, the information will be retained in order to support future trend analysis.

2. That there is a need to take action in order to address the concerns raised and that once this is taken it is unlikely that the concerns will recur. Monitoring arrangements should be agreed and the findings should be logged with the Quality Unit so that progress can be regularly reviewed.

3. That the enquiry has identified further evidence which indicates that the concerns are of a sufficient severity to require a wider investigation/action planning process to ensure that a sustained improvement is achieved. A decision around the most appropriate stage to manage the concern would be made by the Quality Unit who would also provide guidance and where appropriate support in taking the next steps.

Stage II: Local Faculty/Training Programme Intervention

Concerns are managed under stage II either where there is evidence that the action planning undertaken at stage I has not fully resolved the concerns or where the initial evidence received is triangulated. In addition, stage II may also be appropriate where a higher level concern has de-escalated and there is a need for some residual action planning or specific monitoring to ensure sustained change prior to considering closure.

The primary objective of stage II is to investigate the concern through local faculty and training programme collaboration and this may include a visit from the relevant training programme. Action under this stage would typically include, but not be confined to the following:

- Consideration of evidence from all available sources such as the detailed reports arising from GMC National Survey Results and End of placement feedback, or logbook analysis for example.

- Meetings with trainees, trainers and any other relevant personnel in order to further understand the reason behind the concerns and to consider potential solutions. A visit to the site by the relevant training programme may be undertaken at this stage and should include representation from or at least engagement with local faculty structures.

- The establishment of a working group to plan for any significant changes which may be necessary to address the concerns. Such action would be particularly relevant where the management of a quality concern has implications for programme management.

- Development of clear action plans which should include clear monitoring arrangements together with associated timeframes and responsible officers.

Whilst the responsibility for the resolution of concerns at this stage rests with local faculty and training programme structures, it is essential that there is regular communication with the Quality Unit. This ensures that where appropriate indirect support from the Quality Unit can be provided to support the investigation and action planning process and also enables HEIW to fulfil its responsibility to the regulator.

Potential Stage Outcomes:

The following outcomes are anticipated at this stage:

1. That no further action is necessary in which case details of the investigation and findings should be logged with the Quality Unit and the case will be closed. However, the information will be retained in order to support future trend analysis.

2. That there is a need to take action in order to address the concerns raised but that this can be undertaken effectively through local faculty and training programme structures. Monitoring arrangements should be agreed and the findings should be logged with the Quality Unit.

3. That the enquiry has identified further evidence which indicates that the concerns are of a sufficient severity to require a wider investigation/action planning process to ensure that a sustained improvement is achieved. A decision around the most appropriate stage to manage the concern would be made by the Quality Unit who would also provide guidance and where appropriate support in taking the next steps.

Stage III: Direct Quality Unit Intervention

Concerns managed under Stage III of the Targeted Process are usually of a more serious nature either because there are implications for patient safety or because progress from previous action planning processes is not apparent. In these circumstances the primary objective of this stage is to ensure the development of a clear action plan with associated timeframes and explicit monitoring arrangements. Additionally, there are also occasions where Quality Unit intervention may be appropriate due to the need to contextualise an existing evidence base from a lower stage in the process. Where such intervention is required the objective will be to understand the context within which the concerns are raised with a view to establishing whether or not action or closer monitoring is necessary.

Concerns at this level may have escalated or de-escalated through other stages or in those instances where there are significant implications for patient safety the issue may be managed at this level in

the first instance. The management of concerns at this level will be led by the Quality Unit in close collaboration with the relevant training programme lead. Engagement with senior LEP, (Local Education Provider) management as well as local faculty structures is a key feature of this stage and may be achieved by one of the following mechanisms:

- A HEIW Targeted Visit which will typically include meetings with trainees, lead trainers and senior LEP management. The nature and focus of a visit will be dependent upon the rationale for triggering a more formal review. Gathering additional evidence through meetings with trainees and lead trainers is common in a visit particularly where the aim is to contextualise the concern or to review progress. However, there may be occasions where the currency of the evidence base is deemed to be sufficient and in order to minimise the burden of inspection the visit will focus upon meeting with key representatives without the need for interviewing trainees. The HEIW panel composition for the visit will typically include but not be confined to the following representatives:

  Typical HEIW Panel Composition:
  - Chair, (Postgraduate Dean or alternate)
  - Quality Unit representative
  - Training Programme lead, (Where concerns are likely to impact upon trainees from multiple programmes, it would be appropriate to have a lead from each programme).
  - Faculty Lead
  - Lay Representative
  - Royal College Representative; (This will usually apply where there are specific concerns around exposure to the curriculum, where the College have also raised concerns or there is a particular need for specialty externality).

  The panel chair will be responsible for deciding whether the short-notice absence of any key panel member constitutes grounds to postpone the visit.

  Where trainee interviews are required as part of the process the Quality Unit will liaise with the relevant Postgraduate Centre to ask for their support in co-ordinating this locally reminding trainees that they have a professional responsibility to attend wherever possible.

  The list below provides an overview of the LEP, (Local Education Provider), representatives that the HEIW panel will typically ask to meet with as part of the visit process. However, the LEP may also directly invite other LEP employees whom they consider to be relevant to the process. In the event that the LEP would like to include representatives from outside of the organisation this will only be permissible with prior agreement of the Postgraduate Dean or his alternate.

  Typical LEP Representatives:
  - Assistant Medical Director, (Education & Training)
  - Clinical Director
  - Lead trainers
  - College Tutor or equivalent
  - Directorate Manager

HEIW will have the responsibility of ensuring that the Medical Director is notified that a new issue is being managed through a Quality Unit led visit process. The visit panel chair will provide a verbal summary of the key findings to the LEP on the day of the visit and this will be followed by a formal report which will provide more detailed information on the findings together with the recommendations. In the event that particularly urgent action points are identified at the visit then a summary of these will be emailed to the LEP whilst the report is being prepared in order to prevent any delay to the action planning process. In addition following the visit process the Quality Unit will ensure that the Chief Executive Officer and the Medical Director of the relevant LEP receives a copy of all visit reports.

- There are occasions where the timeframes associated with the logistics of a full visit process mean that a swifter alternative approach to the management of a training concern may be necessary. This is particularly pertinent where there are significant implications for patient safety which require urgent escalation. In such cases direct engagement between the Quality Unit and senior LEP management would be considered to be the most appropriate course of action. This may be verbal in the first instance with written follow up. In such circumstances there will be regular contact between HEIW and the LEP throughout the action planning process.

Action plans submitted by LEPs in response to training concerns at this level will be reviewed by the Quality Unit usually in collaboration with the relevant training programme lead. In the event that further clarification is required then this will be communicated to the LEP in writing with a deadline for response. Action planning around the concerns may require additional meetings in the form of a task and finish group or local planning meetings.

Regardless of whether or not a formal Targeted Visit is undertaken at this stage planned monitoring of progress will be a key feature at this stage. This may be undertaken through a formal route such as a repeat visit or it may be deemed appropriate for trainee interviews to be arranged separately and should include representation from the faculty team; this should normally be in liaison with the relevant training programme lead. In addition, paper based evidence sources may also be considered as part of a monitoring process.

Potential Stage Outcomes:

One of the following two outcomes is anticipated at this level:

1. That the action planning process has delivered improvements but there is a need to ensure that the improvements are sustained. In such cases specific monitoring arrangements would be identified and the issue could be de-escalated to Stage II. Closure would not be considered to be an appropriate option for a stage III concern.

2. That there are ongoing challenges in ensuring the delivery of a sustainable solution and specific regulatory input is required. In such circumstances concerns will be escalated to stage IV of the process.

Stage IV: Enhanced Monitoring

Escalation to Enhanced Monitoring would usually be deemed to be necessary for those training concerns which are particularly complex in nature or where there have been challenges in delivering

a sustainable solution. The key feature of this stage is that whilst the concern is still being managed under the HEIW's Targeted Process, there is explicit regulatory input. Regulatory input can be beneficial for complex concerns as there is the ability to draw on experience from similar challenges in other parts of the UK. In addition, regulatory input will also inevitably enhance the level of scrutiny both around the concern itself and the management of that concern. Enhanced Monitoring concerns may be published on the relevant regulator's website in order to enhance transparency but the wording reported on the website would be agreed between the regulator, HEIW and LEP.

Concerns may be escalated to this level directly by HEIW or the relevant regulator may deem enhanced monitoring to be necessary where sufficient assurance around the management of a concern cannot be provided. Regulatory involvement may include a physical presence at visits or may be undertaken remotely.

Typical activity at this stage would be similar to stage III but with the added input of the relevant regulator.

Potential Stage Outcomes:

One of the following potential outcomes is anticipated at this stage:

1. Action planning and progress monitoring.

2. Escalation to regulatory processes - this may be done on the request of the HEIW or the regulator may deem it necessary to invoke their own processes if they are sufficiently concerned about progress.

3. De-escalation to another stage in the process for ongoing monitoring to ensure improvements are sustained. As with stage III of the process direct closure from a concern at this level would never be deemed to be appropriate.

Undermining:

There may be occasions where concerns relating to bullying or undermining behaviour are identified within the evidence base. In such circumstances HEIW will seek to understand whether there are wider factors which have directly contributed towards the concern being raised e.g. a heavy workload combined with significant staffing pressures can generate a pressurised working environment. In those cases the issue will be managed in accordance with the process described above. If there is felt to be potential for the reported or perceived behaviours to merit further local action through the All-Wales Dignity at work policy, then HEIW will liaise with the office of the medical director to ensure that appropriate local action is taken. HEIW will not necessarily be directly involved in the local processes any further but will monitor the situation closely via further feedback obtained from the targeted process.

Cross Border Quality Concerns Management:

Whilst the majority of training programmes quality managed by HEIW are exclusively based in Wales, there are occasions where a cross border approach to quality management may be necessary. In such cases the following principles will apply:

- Where the concern relates to a site in Wales but which has NTN, (National Training Number) holders from outside of Wales the application of the HEIW Targeted Process will apply. However, in recognition of the additional external scrutiny HEIW will seek to include appropriate representation from the relevant Consortium or wider stakeholder group.

- HEIW will liaise with the relevant quality department and where appropriate Postgraduate Dean of the Education Organiser which owns the NTN regarding the nature of the concern, action planning process and monitoring arrangements at key points throughout the process.

- Where the concern is identified at a site outside of Wales but has the potential to impact upon a HEIW NTN holder, the HEIW will work with the relevant Quality Unit.

Conflict of Interests:

HEIW recognises that those involved in postgraduate medical and dental education and training often hold multiple roles which may be related to service and training. In order to enhance transparency within the Targeted Process, HEIW will take all reasonable steps to identify any potential conflicts when composing visit panels, considering evidence or decision making and on the day of the visit. In addition, HEIW would expect that anyone who is aware of a potential conflict and is involved in the Targeted Process would declare this to the Quality Unit. In the event that conflicts are identified HEIW will take steps to ensure that there is appropriate externality within the process specifically to provide additional scrutiny and the visit report will contain details of any conflicts identified during a visit.

Closing Concerns:

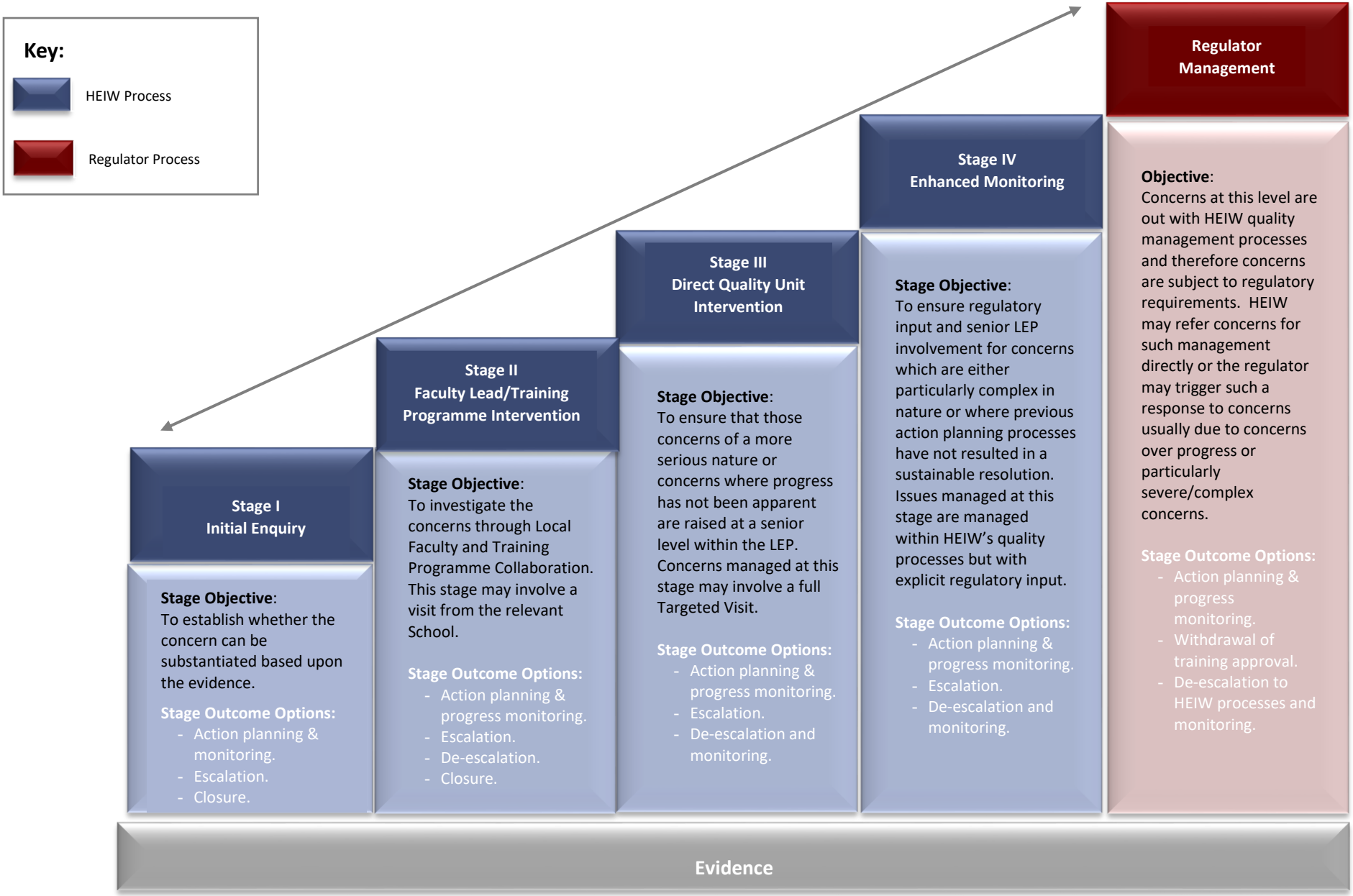
HEIW routinely reviews all training concerns to establish whether further escalation or de-escalation is necessary. Decisions around the closure of a training concern may be undertaken directly by the Sub Dean, (Quality & Governance), Associate Dean (Quality) or Quality Manager. Alternatively, an issue may be recommended for closure and in these cases the following points will used to inform the overall decision around closure:

- Where an issue has been recommended for closure there should be evidence of an agreement between local faculty and training programme structures.

- Closure will only be considered for low risk concerns which are under Stage I or II of the Targeted Process.

- The extent to which there is sufficient evidence that the concerns have been addressed in a sustainable manner and are therefore unlikely to recur. Copies of any relevant documentation such as trainee interview reports, logbook extracts etc. will be considered in the decision making process.

Figure 2: HEIW Targeted Process Overview



Glossary of Terms

ARCP

The Annual Review of Competence Progression (ARCP) is a formal assessment process which, informed by evidence gathered by the trainee and an Educational Supervisor's Structured Report, assesses a trainee's ability to either complete training or to progress to the next level of the training programme. The ARCP process is underpinned by appraisal, assessment and annual planning which precede it. An ARCP panel considers the evidence presented to it to make a judgement as to whether a trainee has attained all required competencies and has made adequate progress. In instances of an unsatisfactory outcome, the panel may make recommendations for additional or focused training required.

College Tutor

The College Tutor has responsibilities for conduction and overseeing training and education within the Local Education Provider. Their main responsibility is to foster and develop the availability of quality training experiences with the support of other colleagues involved in medical education and training.

Local Education Provider, (LEP)

Local Education Providers, (LEPs) is the term that is used to refer to training organisations. Within Wales this would mean the relevant Local Health Board or NHS Trust.

Faculty Lead

Faculty Leads (FLs) are appointed by, and work in partnership with, HEIW to support and deliver high quality medical postgraduate education and training within Health Boards/Trusts. Faculty Leads have varying areas of responsibility:

Faculty Lead for Quality/Educational Governance:
Have specific responsibility for systems of quality control and implementation of the General Medical Council's standards across the LEP. They work with departments where there are concerns regarding the quality of training and are responsible for promoting and sharing good practice.

Faculty Lead for Trainer Support:
Their role is to ensure systems for identifying and supporting all Clinical and Educational Supervisors across the Health Board, including helping to support and organise training events for trainers.

Faculty Lead for Trainee Support:
They have specific responsibility for ensuring the provision of appropriate support mechanisms for trainees and the promotion of the 'trainee voice' and trainee engagement with quality improvement initiatives.

Regulatory Organisations

- **The General Medical Council (GMC)**
  The GMC have sole statutory responsibility for the quality assurance of postgraduate medical education and training. In discharging this responsibility the GMC has authorised Deaneries/LETBs as the organisations who have accountability for the quality management of postgraduate medical educational and training. Therefore all quality management activity for postgraduate medical education and training is undertaken within the context of the GMC's regulatory framework. In undertaking its quality assurance activity the GMC has endorsed HEIW's approach to quality management.

- **The General Dental Council (GDC)**
  The GDC has responsibility for the regulation of dentistry within the UK although comprehensive standards have yet to be finalised. Whilst the GDC's approach to the regulation of education and training is less well developed than in medicine it is anticipated that this will increase in the future and this will be supported by a single HEIW quality framework.

- **Healthcare Inspectorate Wales (HIW)**
  Healthcare Inspectorate Wales is the independent regulator of healthcare in Wales and its inspection activity therefore includes the service within which medical training takes place. Whilst HEIW is not accountable to HIW, given the clear interrelationship between service and training a link has been formulated. This link which is underpinned by a memorandum of understanding provides HEIW with a mechanism to share appropriate information in recognition of the need for a patient-centred approach to quality management.

Risk

Risk is concerned with unknown events that may impact upon the ability of an organisation to meet its objectives. The Institute of Risk Management defines risk as, 'the combination of the probability of an event and its consequences'. Within the context of managing the quality of postgraduate medical and dental education and training a risk is considered to be the extent to which there is or is likely to be a deviation from national standards.

Risk Management

HEIW utilises a risk based approach to managing training concerns. This enables us to prioritise our activity and assures that our quality activity is focussed where it is needed the most. Risks are identified where evidence sources indicate that a training post or programme may not be meeting national training standards and there is a risk to patient safety. Risks may be raised by anyone either inside or outside of the postgraduate medical and dental education and training community. Risk reports are produced to ensure transparency and these can be used as a tool for local quality control and ratings are regularly reviewed based upon evidence that has been obtained through monitoring. Risk reports are formally disseminated to training programme leads and Local Education Providers three times a year. The reports provide information on all of the areas of concern that are being monitored by the HEIW's Quality Unit at any given time and include a risk rating for each issue which

is based upon the severity of the issues and the probability of it affecting the quality of training. Further information is available within the HEIW's Risk Management Process.

Quality Management Framework

- **Routine Component**
  HEIW undertakes annual commissioning visits to LEPs. This process facilitates a strategic discussion around the commissioning and de-commissioning of training posts as well as providing a mechanism to consider the educational environment. In addition, HEIW also has an Annual Training Programme Reporting Process which is based upon a self-assessment against the regulator standards. The process includes a feedback process in order to enhance the governance arrangements within training programmes.

- **Responsive Component**
  The responsive component of the quality management framework is the mechanism by which concerns around the quality of training are managed as and when they arise rather than waiting for routine processes.

Quality Assurance

Quality assurance is the principal activity which both quality management and quality control feed into. Quality assurance is process orientated and comprises all of the policies, standards, systems and processes which have been implemented to ensure confidence that outcomes will meet quality criteria. Within the context of postgraduate medical and dental education and training in the UK quality assurance activity is the responsibility of the relevant regulatory organisation.

Quality Management

The term quality management refers to the arrangements that an organisation utilises to ensure that postgraduate medical education and training are meeting national standards. The arrangements are usually conveyed in a quality management framework which provides an overview of all of the structures which have been implemented to enable an organisation to discharge its quality management responsibilities. Quality management is the responsibility of the HEIW.

Quality Control

Quality control activity is outcome focused and is therefore primarily concerned with the evaluation of whether or not the product meets a set of predefined criteria. Within the context of postgraduate medical education and training quality control is the responsibility of the Local Education Provider and Training Programme Leads to consider quality against national standards.