U.K. Radiopharmacy Group

Key Performance Indicators (KPIs) in Radiopharmacy

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Introduction

"It is not possible to manage what you cannot control and you cannot control what you cannot measure!" (Peter Drucker)

Performance measurements are fundamental to the management of a Radiopharmacy or Positron Emission Tomography (PET) production unit and may be used to underpin the continuous improvement principles required by EU Good Manufacturing Practice (GMP). The measurement of performance allows identification of any gaps between the current and desired or required standards. These measurements can then be used as an indication of progress in closing the gaps. Careful selection of Key Performance Indicators (KPIs) is useful in identifying precisely where to take action to make improvements.

One of the biggest challenges in setting KPIs is selecting what to measure and not to get lost under a barrage of targets. It is important to discern quantifiable factors that are connected to the success of operations. Thus, the right performance measures entails identifying the area of operation which you either need to monitor or the area in which you wish to improve performance.

Different units will have specific parameters which they deem useful to them. However, it is important to note that there are core standards which should be considered when assessing and measuring regulatory compliance. These include performance of the Quality Management System – for example, percentage of quality deviations which are closed out within the allotted timeframe. There will also be some standards which relate to the quality of the service from a different angle – for example, number of products supplied by the allocated time. Assessment of performance against both of these targets is important in quantifying the overall quality of the service. Supply of beautifully prepared high quality products which are always half an hour late will not be perceived as a high quality service; neither would timely but incorrectly made products.

Laying out the operational process might be useful when developing the KPI to allow the operational goal to be met. KPIs should be created using the SMART criteria (1):

SPECIFIC: each KPI should have a specific purpose and target a specific area for improvement

MEASURABLE: KPIs should be expressed quantitatively to be able to quantify the team's progress

ASSIGNABLE: the desired result must be realistic and achievable

RELEVANT: indicators must be applicable & easily understood

TIME LIMITED: performance should be measured over a relevant time frame

KPIs are more likely to improve operational performance if the measure is clearly communicated and all stakeholders understand them. It is important that the team is aware what is being measured, how it is calculated and what their role in it is in order to make a positive impact to the KPI.

Care should be exercised when introducing KPIs so that making the target does not become the sole focus of the production/preparation team and quality of production is not adversely affected. For example a KPI might be set to ensure > 95% of injections are prepared within a particular time prior to the patient's appointment time. In an effort to comply with this KPI it would be considered better to exercise caution so that the correct product is supplied a little late on occasion rather than the wrong product on time.

Types of KPIs

A variety of KPI's may be useful in a Radiopharmacy setting. These may be classified as:

- Managerial – capacity issues (e.g. number of products made, number (%) supplied on time)
- Production failures (e.g. product fails analysis)
- Product recalls and complaints.
- GMP processes such as environmental monitoring out of specifications (e.g. number of colony forming units detected on finger dabs), pre- and post-release error rate, deviation frequency or time to close corrective and/or preventative actions (CAPA)s / deviations.

Scoring Performance or Target Levels

KPIs may be scored in a variety of ways. The performance of a given parameter may be simply expressed as a percentage e.g. number of errors expressed as a percentage of number of doses prepared. A simple limit or target value may be assigned to this – for example the number of errors detected at release should be < 5% of the number of doses prepared.

Another method might be to use the 'traffic light' system to indicate if a system is in control e.g. red (out of specification), amber (alert level) and green (compliant). For example the number of CAPAs closed off in an agreed timescale may be scored as green when > 95%, amber when between 90% - 95% or red if <90%.

Recommendations

The choice of KPIs introduced within a department is driven by regulatory and operational requirements. Below are three core KPI topics that it is felt would be most useful in the Radiopharmacy and PET production setting. Following this a breakdown of other suggested KPIs which may provide a useful means of monitoring the performance of the Quality Management System and in addition other useful parameters to measure that relate to the performance of the facility itself. Finally, a list of additional operational KPIs that might be considered useful within a Radiopharmacy or PET production setting.

Core KPIs

1. Time taken to close out Deviations / CAPAs (measured against locally agreed timescales); number of CAPAs versus number still open.
2. Time taken to close out complaints (measured against locally agreed timescales for complaint type e.g. service complaints versus quality complaint).
3. Adherence to the capacity plan (both frequency of excursions from plan and extent of that excursion)

Further Suggested KPIs for monitoring the Quality Management System

A traffic light system could be used with the following with green being in control (e.g. >95%), amber being at alert levels (e.g. <95%; >92.5%), and red being at action levels (e.g. <92.5%)

- Errors – number of errors detected prior to release, at release and after release (or other key points in the process)
- Quality Exception / Deviation Reports – number still open, number of investigations overdue, number of actions overdue
- Change Controls – number awaiting approval; number awaiting approval (of proposal and action plan); number with overdue actions.
- Validation Plans – number awaiting approval of protocol; number still open
- Documentation – number beyond review date
- Audit Action Plan(s) – number audits performed on time; number of completed/overdue actions for internal and external audits e.g. MHRA, EL(97)52.
- Product Quality Review – number actions open; number completed/overdue actions
- Product recalls – number of recalls
- Complaints – number received; number still open with respect to number received or number resolved

KPIs to Monitor Performance of the Facility and Equipment

(a) Physical Monitoring

- Isolator Leak test failures
- Air Handling Unit compliance
    - Pressure across HEPA filters: monitor trends as a percentage of maximum
    - Temperature
    - Relative Humidity
- Laminar Flow Cabinet performance parameters, such as air flow

(b) Microbiological Monitoring

- Sessional and finger dab results (Grade A): e.g. Number of Colony Forming Units (CFUs) per plates. One approach could be to have a target average < 0.05% for the number of occasions above action level.
- Other graded rooms: number of Out Of Specification (OOS) results – alert and action levels relevant to the grade of room.
- Number of action and alert level breaches
- Number of environmental deviations (or CAPAs) raised.
- Number of sterility assurance tests that have passed or failed (e.g. process validations, end of session broth fills, operator validation tests, sterility tests)
- Frequency of objectionable organisms detected.

(c) Other Equipment

- Fridges, Freezers and ambient temperature – number of temperature excursions, degree of temperature excursion.
- Planned Preventative Maintenance on Air Handling Unit performed to schedule
- Calibration of Dose Calibrators
- Calibration of other equipment, such as temperature monitoring system

Additional Recommended KPIs

Below is a selection of possible KPIs that might be useful within your own working environment to satisfy the requirements of management, requirements of legislation or as a monitoring tool

to help with specific goals for promoting continuous improvements. Some may satisfy more than one of these requirements.

- Percentage of injections supplied that meet the requirements of local Diagnostic Reference Levels (DRLs) at the booked administration time (e.g. greater than 95% of injections are prepared with 90 to 100% of DRL).
- Percentage of injections supplied within agreed time prior to the patient appointment time (e.g. greater than 95% of injections are supplied 20 minutes prior to documented appointment time or by injection time).
- Percentage of deliveries made by the agreed time
- Number of product failures or rejected batches (e.g. in Radiopharmacy number of products not meeting required radiochemical purity; in PET, the synthesis success or failure rate for individual PET radiopharmaceuticals)
- Training completed – for example, % of staff trained in new SOPs
- Broth tests done within allocated timeframe
- Cleaning records fully completed
- Radioactive waste disposed of within allocated timeframe

Monitoring and Reporting KPIs

In order to make compliance easier, KPIs should be easy to measure and if possible, should include information which is being captured anyway. Having a KPI on how well you are doing with your KPIs is something to be avoided!

Once the information has been captured, it is important to consider what is done with it. Sharing within the team to allow reflection, learning and improvement if necessary is essential. Equally, good performance should be celebrated and encouraged.

Sharing of KPI data outside of the department is an important part of the organisation's governance structure. If KPIs are not being met, this can form the basis of a discussion on the reasons for this. For example, are the KPIs reasonable? Are there too many? What are the reasons the KPI isn't being met? Is there an underlying problem with resource or capacity which needs to be addressed? Poor KPI data can in some cases be an indication that processes need to be reviewed or additional resource is needed.

Conversely, achievement of KPI targets can help to boost the department's profile, and make it a more attractive proposition for investment. Either way, monitoring and reporting KPIs is an essential part of the management of the Radiopharmacy.

References

(1) Peter Drucker, Management Review 1981
(2) EU GMP European Commission (2015). The rules governing medicinal products in the European Community. Vol IV. Good Manufacturing Practice for medicinal products. Available at :**http://ec.europa.eu/health/documents /eudralex/vol-4/index_en.htm** (accessed 26 February 2016).