AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

Individual Patient Funding Request (IPFR) Quality Assurance (QA) Group Audit
9 May 2024 via Teams

Meeting minutes

Present:

Group members	Observers
Professor James Coulson (Director, AWTTC) Chair	Mrs Gail Woodland, AWTTC
Dr Michael Thomas (Consultant in Public Health Medicine, HDUHB)	Ms Rosie Spears, AWTTC
Mrs Ann-Marie Matthews (lead IPFR co-ordinator)	Miss Laura Phillips, AWTTC
Ms Rebecca Boyce (Health Technology Wales representative)	
Mrs Pam James (Lay representative)	
Mrs Jane Barnard (Lay representative)	

The meeting started at 1.30 pm

Introduction:
Members were welcomed by the Chair and asked to declare any interests. Interests were declared by Ann-Marie Matthews for Aneurin Bevan University Health Board and Dr Michael Thomas for Hywel Dda University Health Board. Applications from the period January to March 2024, one from each panel, were considered at the meeting.

Feedback from previous QA meeting:

Feedback from Cardiff and Vale Panel
Rosie Spears informed the group that Cardiff and Vale have successfully appointed Mr Guy Blackshaw as Vice Chair. They anticipate this may help getting letters out to clinicians within the five-day deadline in circumstances when the Chair is unavailable to sign off the rationale.

Feedback from Swansea Bay Panel
Gail Woodland reported feedback following comments made in the February meeting report to Swansea Bay (SB). The QA group did not consider the case assessed at the time to have met quoracy, it was requested as ‘soon’ to be considered within three weeks and was considered by Chair’s action. The panel were advised that unless a request is urgent it should be considered by a full panel. SB responded that, although they had a panel meeting scheduled within the timescale (for prior approval requests), they were uncertain that it

would be quorate for IPFR requests. The request had therefore been considered by Chair's Action ahead of the meeting. The meeting had in fact attained quoracy; Gail advised that it would have been preferable for the request to be scheduled for the panel meeting and in the event that quoracy was not achieved, then considered by Chair's action. Therefore, the QA group report remains unchanged.

There was also discussion with the SB panel with respect to information that had been provided to the panel to ratify a Chair's action decision. The QA group felt that the information provided to the panel members was not complete and SB confirmed that some of the information had been omitted. There was some discrepancy as to the interpretation of the role of the panel in this circumstance, the panel report remains as it was.

Table 1. Criteria used for IPFR quality assessment audit

Process	Evidence to assess whether the process has been adhered to	Criteria
Application process	IPFR application form, clinic letters/associated emails and IPFR panel minutes	Was this an appropriate request to consider via the IPFR route?
		Was the IPFR application form signed?
		Was there sufficient information provided for the case to proceed to panel?
	Date of receipt of IPFR versus date of IPFR meeting versus urgency ticked	Was the case taken to panel within the timescale stipulated on the application form?
Panel process	IPFR panel minutes	Was the panel quorate?
		Was the discussion held by the panel in line with the decision-making guide?
		Was the decision and rationale for the decision clearly described in the minutes?
Decision process	IPFR panel minutes, IPFR decision letter to clinician, IPFR decision letter to patient, date on letter vs. date of meeting	Did the letter to the clinician clearly state the decision and explain the reason for the decision?
		Was the decision letter sent to the clinician within 5 working days of the panel's decision?
		Did the letter to the clinician state the review deadline date, and enclose the

		review form and guidance notes where applicable?
		Was the letter to the patient sent within 5 working days of the panel's decision?

IPFR cases:
The group went through each panel IPFR application in randomised order. The group looked at each criterion in turn and were asked as to whether the criterion was met, not met, undecided or not applicable. For any criterion that wasn't met the group provided reasons for their opinion. The group were also encouraged to make general comments which could be shared across all panels, in particular examples of good practice and any common themes highlighted by this audit process.

The group were pleased to note that, five of the eight panels met all of the criteria.

All of the cases assessed met the urgency timelines requested on the form. For all requests considered by panels in the quarter January to March 2024, six panels met the urgency requested in all cases. One panel did not report the urgency and the other met urgency in 69% of cases.

The group considered that use of Chair's action by one panel was inappropriate as the timescale stipulated on the request was for consideration within three weeks of receipt. This should have allowed sufficient time for the case to be considered at a subsequent panel meeting, therefore this case was considered as 'non-quorate'. The other seven panels were quorate or used Chair's action appropriately for urgent cases.

In general, the group felt that the panel discussions were in line with the panel making guide, although value for money discussions still appear to be limited. In one case the discussion held by the panel was not considered to be in line with the decision-making guide. The case had been considered under part 9B of the application form using the new IPFR Policy. This policy is yet to be implemented and there is some ambiguity around the policy wording with relation to part 9B. The QA group assess the criteria in line with the decision-making guide and noted that the panel had not considered if the patient would derive greater clinical benefit from the treatment than other patients with the same condition. It is therefore possible that the panel could be making decisions misaligned with the other panels.

This issue had already been identified as a discrepancy in decision making with the panel in question. Ann-Marie Matthews and Gail Woodland have discussed the issue with the panel chair. The panel will continue to interpret the policy for part 9B in terms of the treatment benefit for the patient compared with available treatments. Consideration as to the patient's clinical presentation being significantly different to other members of that population

will not be discussed. The panel does not refer to the decision-making guide as in the new policy it appears as an Appendix to the policy rather than the body of the policy. The revised policy is due to be implemented by the panel in June 2024, in the meantime, Gail Woodland and Ann-Marie Matthews will consult with Welsh Health Legal Services to clarify the wording in the policy and if necessary revise the wording to ensure there is no ambiguity.

With respect to the case assessed, the QA group will feedback to the panel that they do not consider that the panel discussion was in line with the decision-making guide. They request that the current policy and decision-making guide is followed until the new policy is implemented across all panels in Wales.

The rationale was not described fully in the minutes for one panel, it was unclear if the panel had considered the potential cost of treatment beyond the initial trial period. Should the patient remain on treatment this would incur much higher costs and once a patient is commenced on treatment it would be very difficult to overturn an approval on subsequent review. With this in mind, it is recommended that costs are considered for the full treatment course. The discussion referred to a possible reduction in cost in the future on loss of patent of the medicine, this was not considered to be appropriate as a significant reduction in price could not be guaranteed in all cases due to availability of generics.

In two cases the letter to the clinician was not sent within the five-day deadline. In those two cases the clinicians had been informed by email on the day of the decision. These were both approved but should they have been non-approvals this may have caused issues should the consultant wish to request a review of the decision. In another case the clinician informed the panel that the patient had sadly deceased before the decision letter had been sent therefore no letter was required for the clinicians or patient.

Five panels sent a letter to the patient within the five-day deadline. One panel did not send a letter to the patient; the clinician letter had been amended to state that the patient had not been informed. The panel will be informed that this contravenes both the current and new policy.

There were a few comments to be shared across all of the panels. The group would like to note for all panels that the whole treatment costs should be considered, given that once a treatment has started it would not be reasonable to stop if it is shown to be providing benefit.

The group would also like to highlight the difference between cost effectiveness and value for money. It is unlikely that cost effectiveness can be demonstrated for an IPFR application, unless there is a specific cost effectiveness paper or economic model utilised that relates to the specific patient group identified. The economic considerations as described in the decision-making guide should be used to decide if a treatment is reasonable value for money.

IPFR panel attendance
There was no feedback from panels for this meeting, Pam James is planning to observe at the next CTMUHB panel on the 21 May. Tom Winfield, newly recruited health economist at AWTTC, observed the ABUHB panel in the first week of May. AWTTC colleagues will request feedback and report to the group at the next meeting.

IPFR workshop
Gail Woodland informed the group that there were over 60 people registered to attend the workshop. The cases for consideration by mock panels in the afternoon have been circulated and the rest of the sessions are prepared and ready for the day.

AOB
The Chair introduced the subject of the review of the policy by JCC (formally WHSSC); in particular a letter from Welsh Government dated 17 April agreeing to adopt the new policy. The group highlighted that the letter refers to a letter dated 6 February from the former Managing Director of WHSSC which included enclosures. The QA group queried as to whether it would be possible to have sight of the letter. Rosie Spears will follow this up.

Future IPFR QA meetings

The next IPFR QA meeting is 25 July 2024 at 1.30-3.30
The Chair closed the meeting at 3.30 pm.