

THE IFR PROCESS

Governance arrangements,
evidence collection, panel meetings
and reasons

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Judicial Review - Lawful Decision Making

- Focus on process and not attack on outcomes

“.. it is appropriate for the court to subject the decision to refuse funding for the treatment (and thus in practice the treatment) to rigorous scrutiny”

R (on the application of Rogers) v. Swindon PCT [2006] EWCA Civ 392 [The Herceptin case]

NHS Constitution

- Sets out key principles
- Does not change the fundamentals
- Focus on procedural rights:

“The NHS commits to make decisions in a clear and transparent way, so that patients and the public can understand how services are planned and delivered.”

Legal risks of an IFR process

- Never say “No”
- If you are going to say “No” ensure that you:
 - Collect the all the evidence and put before panel.
 - Get the process right: Decision taken in accordance with the policy.
 - Get the communication right: Letters to patient not just internal NHS issue.
 - Have a complete and defensible audit trail.
 - If JR threatened, seek legal advice early. Its cheaper to re-run the process than pay for a JR.

In broad terms what should an IFR Policy do?

- Define Remit of Panel
 - Logic or compassion
 - Consistency or inconsistency
 - Which cases make it to panel?

- Places emphasis on
 - Individual condition being exceptional
 - More benefit from investment than the average patient
 - Is this end of life care or not?

- Beware Policy Making and Precedent Setting by individual cases

- Make provision for taking into account all general target duties on NHS bodies – those in section 14 of NHS Act for CCGs (often neglected)

Overall shape of procedure described in policy

- Individual Funding Request Policy
 - Who takes the action?
 - Screening Stage
 - Funding Request Panel
 - Appeal Panel
 - Documentation
 - Pro Forma Questionnaire
- Duty to give reasons in writing to patients

Overview of a typical process (from NHS England)

- <https://www.england.nhs.uk/wp-content/uploads/2017/11/ifr-infographic.pdf>

Examples of matters a policy might cover

- Purpose
- Responsible Commissioner
- Delegated Authority
- Roles and Responsibilities
 - IFR Team
 - IFR Senior Manager
 - Clinical Applicant
 - Provider Organisations
 - Clinical Commissioning Group
 - IFR Panel and Process Review Panel
 - IFR Panel and Process Review Panel Chair
 - IFR Authorised Officer
 - General responsibilities –
- safeguarding adults and children
- Communication
- Submitting a request
- Consent
- Photographic evidence
- Screening
- IFR Panel
- Clinical Exceptionality
- Clinical Effectiveness
- Good Use of NHS Resources
- Non-clinical and social factors
- Cohorts of patients
- Service developments (or Commissioning Policy Decisions)
- Personal Health Budgets
- Private Service Providers
- Urgent treatment decisions
- Retrospective funding
- Funding decisions
- Decision expiry
- Reconsideration of decisions
- Appeal/Process Review of the decision
- Information Governance and Confidentiality
- Equality Statement
- Review and Monitoring of this policy and procedure
- Documents which have informed this policy

Managing the flow of requests: screening

- The only cases that should come before the panel for an individual decision should be:
 - Genuinely unusual conditions for which there is no policy
 - Usual conditions which present in unusual ways (“I cannot tolerate the usual treatment because....”)
 - New medical developments
- Policy should say that we do not fund new developments outside the various commissioning policies unless exceptional.
- Can use a screening process to filter
 - Pre screening: more administrative
 - Screening: arguability threshold potentially

The Panel

- Funding Request Panel
 - Composition of Panel/Delegated Authority
 - Criteria
 - Attendance by Patients/Clinician

Appeals in IFR Cases

- Should you have an IFR Appeal Process?
- If so:
 - Appeal on Process Only/Re-Hearing
 - How do you get both consistency and good governance
 - What About New Information?
 - [Guidance says send it back to panel]

What are Exceptional Circumstances?

- Exceptional means “far beyond what is usual in magnitude or degree” and “surpassing what is common or usual or expected”
 - Better not to define what exceptional means
 - Beware of setting precedent by setting the bar too low
- But policy should say this is a threshold
 - Still have to consider clinical effectiveness and cost effectiveness
- Should mean few cases qualify

Judicial Review – What does this mean in practice

- Review by the Court of the legality of decisions not a merits appeal.
- Paper based review – no evidence in person
- Interim relief
- Mainly focused on duty to give reasons:
 - Must explain what is relevant,
 - ignore the irrelevant and
 - reach a reasonable decision
- **And if you do all that you will be fine!!**

What does this mean in practice?

- Have a policy on making both general commissioning and individual decisions
- Follow the policy
- Make sure that the right body is constituted to take a decision
 - It has all the relevant information
 - It has proper minutes of its deliberations
 - It reaches a decision
- Make sure the CCG explains the real reasons for the decision.

Procedural impropriety and Irrationality

- If you have a policy, follow it
 - If you decide to deviate from it, explain why
- If there is NICE or DH Guidance follow it
 - If you decide to deviate from it, explain why
 - If it is a TAR you must follow it unless exempted
 - Cannot say No simply because no NICE Guidance

Decision Making and Record Keeping

- Lawyers and paper!
- Audit Trail
- Fairly considered the application
- Conducted reasonable inquiries
- Reached reasonable conclusion
- Properly considered exceptionality

Decision making and Record Keeping

- Minutes
- Duty to give reasons under Directions
- Address all key issues
- Core facts
- Relevant issues
- Irrelevant issues

Decision Making and Record Keeping

- Decision letter
- Scope for attack?
- Transcript
- Notes edited by Chairman

Some pointers ..

- Clear Audit Trail From Request – Decision
- Follow Policy
- Robust Chair (At Each Stage)
- Avoid ‘Rule of Rescue’
- Ensure All Those Involved in Process Understands Process
- Communicate with Clinician and Patient
- Put yourself in the best position to defend your actions

Conclusions

- Understand clinical issues and legal risks from the start
- Get good clinical and legal advice early
- Don't defend the indefensible
- Stand your ground on equity issues
- Always be prepared to accept that resources lie at the heart of the decision
- You can always start the process again

Thank you for listening

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