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Introduction to the IFR process and how it fits with CCG commissioning policies and patient rights

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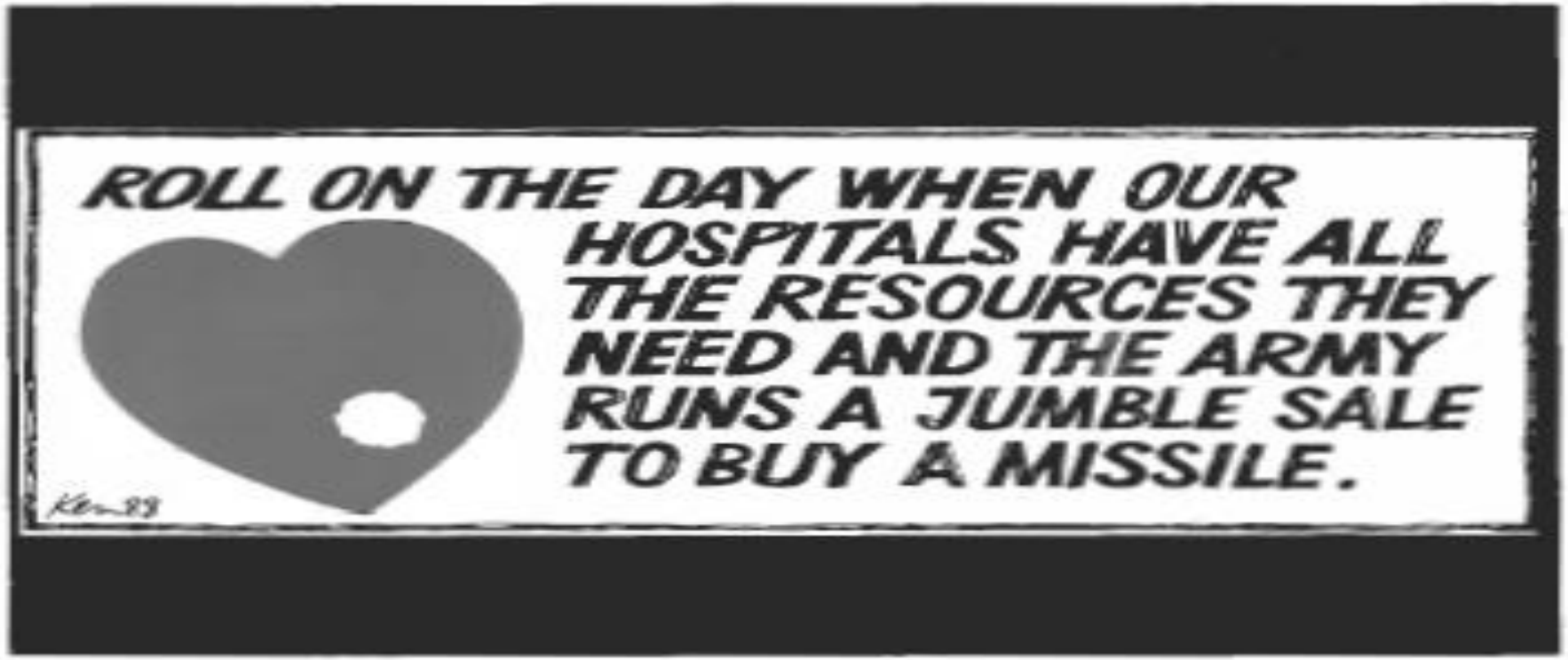
What do the public want?



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Is there any chance NHS will ever get there?

- Demand for healthcare will always exceeds the NHS's ability to supply services

- A problem that cannot be solved
    - Ageing population
    - Increased public expectations
    - New technology and drug company economics
    - An increased supply of healthcare will create its own demand

- CCG legal duty to break even

… and

- New Drugs developing all the time
- Triangle of:
  - Drug companies who fund….
  - Pressure Groups who raise expectations of patients ….
  - Who challenge CCGs with money and resources provided pressure groups….
- Triangle of Influence: To increase pressure to purchase drugs from drug companies
  - DHSC is conflicted

NHS Commissioning

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- Commissioning is a continuing cycle of activities that includes:
  - assessing the needs of a population;
  - analyzing “gaps”;
  - setting priorities;
  - developing commissioning strategies;
  - influencing the market to best secure services;
  - and monitoring and evaluating outcomes.

- Main commissioners are NHS England and clinical commissioning groups (“CCGs”)

Commissioning key challenges: resource based rationing

- Delivering a comprehensive health service is only a target duty
- Tension between promoting a comprehensive healthcare service and duty to break even
- Primary commissioning duty on CCGs - Section 3 NHS Act 2006 - duty on limited to providing services necessary to meet all **reasonable** requirements. Not automatically meeting **all** requirements. Entitled to take into account resources.
- Political tensions as a result
  - Do resources go to the consultants and patient groups who shout loudest?

Commissioning key challenges: resource based rationing

- **In general**, commissioning is about population medicine, and rarely about individual patients

- Problems arise because demand for clinically effective treatments for individual patients vastly exceeds finite budgets of commissioners to fund such treatments.

- Given the full support of the Court of Appeal in *R v. Cambridgeshire Health Authority ex parte B [1995] 1 WLR 898*

- No duty of care owed by CCG to patients
  - Court recognises that you should take hard choices

R v Cambridge Health Authority, ex parte B [1995] 1 WLR 898

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"*I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it costs, particularly when a life was potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make.*"

Re J (A Minor)
[1992] 4 All ER 614

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"*I would stress the absolute undesirability of the court making an order which ma have the effect of compelling a doctor or health authority to make available scarce resources (both human and material) to a particular child, without knowing whether or not there are other patients to whom those resources might be more advantageously devoted.*"

Individual funding requests

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- Commissioning about general populations, but what about patients with less common conditions?
- Solution= individual funding requests for “exceptional” clinical circumstances.
- Since case of *North West Lancashire*, clear that unlawful for commissioners not to provide a route through commissioning process to show that their circumstances are “exceptional”
- Now also a statutory requirement under RSR Regs 2012

The law

34.— Duty of a relevant body in respect of the funding and commissioning of drugs and other treatments

(1) A relevant body must have in place arrangements for making decisions and adopting policies on whether a particular health care intervention is to be made available for persons for whom the relevant body has responsibility.

(2) Arrangements under paragraph (1) must—

…

(b) include arrangements for the determination of any request for the funding of a health care intervention for a person, where there is no relevant NICE recommendation and the relevant body's general policy is not to fund that intervention.

Legal status of NICE recommendations and guidance

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- NB patients have a legal right to access NHS-funded treatment described in a NICE Technology Appraisal Recommendations, if they meet the clinical indicators.

- Commissioning decisions/policies should reflect this

- Commissioners are under a legal duty to take into account all other NICE guidance, although they are not under legal duty to implement.

- Does this translate into a legal duty to accept NICE's evidential underpinning? See *Rose.*

The law

35.— Duty to give reasons for decisions

(1) A relevant body must—

(a) publish on its website a written statement of its reasons for any general policy it has on whether a particular healthcare intervention is to be made available for persons for whom it has responsibility; or

(b) where it has not published such a statement, provide a written statement of the reasons for any such policy when any person makes a written request for such a statement.

(2) Where a relevant body—
(a) makes a decision to refuse a request for the funding of a health care intervention for a person; and (b) its general policy is not to fund that intervention,

the relevant body must provide that person with the reasons for that decision in writing.

Why might a CCG not fund a particular treatment?

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- CCG might not have been aware of the need for this treatment/service (this can be true for common and uncommon conditions).
- CCG may have decided to fund the intervention for a limited group of patients that excludes the person making the request.
- CCG may have decided not to fund the treatment because it does not provide sufficient clinical benefit and/or does not provide value for money.
- CCG may have accepted the value of the intervention but decided it cannot be afforded in the current year.

Where do IFRs fit in the commissioning process?

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- Generally speaking, five stages:

1. Joint Strategic Needs Assessment (JSNA)
2. Joint Health and Wellbeing Strategy
3. Annual CCG commissioning plan
4. Commissioning Policies for individual medical conditions which flow from the annual commissioning plan; and
5. Agreeing how exceptions will be made to policies; how ”in year” service developments will be managed; and **adopting a policy for IFRs**.

IFRs: the statistics

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- IFRs are becoming increasingly common.

- Some statistics:
  - 67, 051 IFRs were processed in 2016-2017, an increase of 47% over the previous four years.
  - 52% were approved, up from 43% four years ago

- Postcode lottery:
  - In 2016, Southern Derbyshire CCG received just 14 requests for procedures such as cataract surgery but approved none
  - Stafford and Surrounds CCG processed 2123 requests, including 764 for skin excision, 232 for cataracts and 163 for hip or knee replacement, but approved them all.

Typical circumstances in which patients have need to make IFR

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- Three typical situations:

1. the patient has a rare condition (so the commissioner has no particular policy) and makes the request for funding for the usual way of treating the condition

OR

2. the patient has a more common condition but claims that the usual care pathway does not work for him or her
3. the patient wants to take advantage of a medical treatment that is novel, developing or unproven, and which is not part of the CCG's commissioned treatment plans.

What does “exceptionality” mean?

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- Relevant to situations 2 + 3
- Differing ways of defining
- Often criteria used are:
  - Clinical effectiveness
  - Cost effectiveness
  - There are not likely to be other patients in a clinically similar situation
- Query whether better not to define? Important to leave scope for discretion.

What does “exceptionality” mean?

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- Way often expressed in some policies:

- The patient is significantly different to the general population of patients with the condition in question;
- and
- The patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition.

NHS England definition

- NHS England IFR policy describes exceptionality in a sensible and pragmatic way, which reflects underlying equity considerations:

"*To justify funding for treatment for a patient which is not available to other patients, and is not part of the established care pathway, the IFR Panel needs to be satisfied that the clinician has demonstrated that this patient's individual clinical circumstances are clearly different to those of other patients, and that because of this difference, the general policies should not be applied. Simply put, the consideration is whether it is fair to fund this patient's treatment when the treatment is not available to others. It should be stressed that an IFR is not a route to "have another look" at the general rule, or to protest that the general rule is ungenerous.*"

Rare conditions

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- Situation 1
- Because the CCG has **no** policy, requiring “exceptionality” would be setting the bar too high.
- Question ought to be whether the person has a “reasonable requirement” for the treatment
- I.e.
  - Would it be clinically effective?
  - Would it be cost effective?

Relevance of personal/social factors

- Personal circumstances, or non clinical factors, can lawfully be treated as irrelevant to a decision on exceptionality: *Condliff.*

- *R (Ann Marie Rogers) v Swindon PCT* [2006] EWCA Civ 392 [Herceptin case]:
  - *"Where the clinical needs are equal, and resources are not an issue, discrimination between patients in the same eligible group cannot be justified on the basis of personal characteristics not based on healthcare".*

- Example given by Sir Anthony Clarke: whether a patient had to care for a disabled child - irrelevant

- More on this later from Leon….

When might seemingly ”social” factors actually be clinical?

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- Serious mental health problems – beware of considering psychosocial

- Does a social factor, such as where someone works, somehow translate into a clinical factor or risk?

Some difficult issues

- Orphan Drugs and unusual conditions
  - Do you spend more on someone who has an unusual condition?
  - Is there life beyond John Stuart Mill?
- End of life care
  - What can you do to prevent clinicians following the Rule of Rescue
  - Do you agree “Vast investment in technology at end of life for little if any objective gain”
  - All needs to be reviewed in the light of Richards

Thank you for listening

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