Ethical considerations for IRT in South Africa

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Summary of issues:

1. IRT is a scarce resource and should be used responsibly
2. Rare and orphan disease resource allocation
3. Access to IRT product of choice in public and private sectors
4. Advocacy and addressing disagreements

Fundamental ethical principles

Autonomy, beneficence, non-maleficence, and justice are generally accepted as the four fundamental ethical principles that guide healthcare delivery. Autonomy is self-determination, making one's own choices. Beneficence is acting in the best interests of others, promoting the well-being of others. Non-maleficence is doing no harm or acting to avoid harm. Justice is treating people fairly, impartially, and equitably. Distributive justice refers to fair distribution of resources. These four principles are foundational to the doctor-patient relationship and to the delivery of clinical care.[1]

Principles of resource allocation in healthcare

No healthcare system in the world has sufficient money to afford all the demands placed on it, and decisions regarding fair distribution of these resources must be made. Choosing between different courses of action and allocating resources must be fair or just, as the choices will impact people's lives and may even result in death. These choices occur at a macro-allocation level (i.e., at health system and budget allocation level) and at a micro-allocation level (choosing between patients).

'The characteristics of a fair process can include such things as being clear and open about decisions, the reasons for those decisions, who made them, and the possibility of revising decisions in the light of new evidence or new relevant considerations. In ideal circumstances groups affected by the decisions should be consulted and opportunities for formal appeals against decisions should be provided.'[2] Principles of resource allocation should, as far as possible, be based on the following: equal value to all; getting the most out of available resources; and giving priority to those in need (e.g., priority to those in greatest medical need, priority to the worst-off or most disadvantaged, priority to those at increased risk of harm, priority to those we know have suffered injustice in the past).[2] Many resource allocation decisions are made using utilitarian considerations (maximising benefit) and rights-based approaches of justice.[3]

IRT as a scarce resource

IRT is a limited resource, and its use should be restricted to those conditions where evidence exists for its use. Expert professionals and professional societies are responsible for establishing defensible guidelines for its use and ensuring that IRT is listed in the essential medicines list. In addition,

prescribing of IRT should ensure effective and non-wasteful use of a limited and expensive resource. This is underpinned by the ethical principle of justice.

Rare and orphan disease resource allocation

The principle of non-abandonment holds that it would be unethical to exclude rare and orphan diseases from public healthcare resources. The population of patients with rare diseases is large and therefore cannot be ignored in allocation decisions. 'While neither unlimited funding nor complete abandonment offer an acceptable route for the allocation of resources, it is necessary to adopt a middle course. Here, the major challenge is to address the moral dilemma of 'opportunity cost': resources devoted to the diagnosis, prevention and treatment of rare diseases cannot be spent on the realisation of other healthcare objectives.'[3]

Primary immunodeficiency (PID) is classified as rare disease, although the number of PIDs is large and therefore many individuals are affected. Access to IRT is a fundamental right for these individuals (principle of justice). It is in these patients' best interests (principle of beneficence) and can restore them to full functionality (as per the equal value and priority justifications for resource allocation).

Access to IRT product of choice in public and private sectors

Both intravenous immunoglobulin (IVIg) and subcutaneous immunoglobulin (SCIg) replacement therapy comprise standard of care for patients with antibody deficiency due to a PID or secondary immune deficiency.[4]

The choice of route (IVIg or SCIg) for IRT depends on several factors, including patient characteristics, clinical indication, venous access, side effects, rural or remote location, treatment plan compliance and patient choice. Factors that influence the decision as to whether IVIg or SCIg replacement therapy is the best option for a given patient include availability of Ig delivery systems, appropriate products, patient factors, logistic considerations, patient preference and cost.[4] The ethical principles underpinning these decisions are beneficence, autonomy, and distributive justice. Studies suggest that SCIg is well tolerated and often preferred by patients because it improves quality of life and can be administered at home, but cost considerations and frequency of administration may make it unfeasible. It is important that total cost be taken into consideration in determining the most appropriate route of administration for an individual patient, as well as the fact that this is lifelong therapy and so considerations of the long-term effects of the therapy must also be taken into account (non-maleficence).

Advocacy and addressing disagreements

Patient and professional advocacy groups and societies should engage with the national and provincial Departments of Health and private practice funders to ensure that the most appropriate form of IRT is available to patients, in adequate supply. Education of health professionals is essential to avoid incorrect prescribing and wastage. Patient circumstances may dictate that one form of IRT is preferable, and there should be a mechanism to ensure this and to resolve differences. One way of doing this is the 'Anne of Green Gables' approach, in which 'even the orphans that no one would rationally want to adopt - the Anne of Green Gables-like orphans – acquire a realistic, although small, possibility of adoption'.[3] This would require a ring-fenced budgetary allocation for a small group of

patients who would derive benefit from a particular form of therapy, and who would access it through random allocation.

Conflicts of interest between healthcare professionals, professional medical associations, patient advocacy groups, funders and the pharmaceutical industry will have to be declared and carefully managed.

References:

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