Treatment versus Research: Part 5: Bridging the Boundaries

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INTRODUCTION

For clinicians wishing to embark on research, the obvious choice may be to use their large patient pool, already at their disposal. Gathering information from old files and records is relatively easy and harmless, as long as anonymity and confidentiality are maintained. However, if they choose to conduct investigations on new materials or techniques, their patients could inadvertently and unwittingly become study participants, which raises ethical concerns. This paper aims to clarify the difference between using novel approaches as part of routine clinical treatment and conducting clinical research, and explores the possibilities of straying over the fine dividing boundary, which could lead to "patient experimentation".

CLINICAL TREATMENT

The Online Medical Dictionary defines **Clinical treatment** as "the management and care of a patient by provision of therapy focused on combatting a disease or disorder, or with interventions aimed at improving health".[1] It usually follows accepted standards, and has an expectation of success. Health refers to "the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".[2]

In the dental field, restoration of health can be effected by a number of different treatment modalities.[2]

Active treatment: is immediate treatment of an injury, management of a disease process or provision of pain relief.

Restorative treatment: replaces structures which are missing or have been lost.

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Causal treatment: is directed against removing the cause of the dental problem or disease.

Conservative treatment: provides minimally destructive operative and restorative procedures.

Empiric treatment: refers to treating in a manner that experience has proven to be beneficial in the past.

Rational treatment: is based upon education and knowledge of the disease process, the mechanisms behind the actions taken, and the expected outcome of the remedies or interventions.

Expectant treatment: is directed toward relief of untoward symptoms, while leaving the cure of the disease or healing to natural forces.

Extraordinary treatment: is usually highly invasive and may present with increased burdens and risk to the patient. E.g. provision of osseointegrated implants carries the burden of high costs, time, need for extensive surgical and anaesthetic procedures, potential pain, possible damage to surrounding anatomical structures, and risk of failure or loss. These risks need to be weighed up against the potential benefits for each patient and situation.

Specific treatment: is treatment that has been adapted to suit special patient needs, in unusual conditions, or in peculiar circumstances.

Palliative treatment: is empathetic care in situations where therapeutic interventions are no longer possible, desirable or deemed to be of benefit.

Supportive treatment: is the provision of adjunctive counseling, therapy or aids to augment the initial treatment e.g. bite splints after full mouth rehabilitation.

Preventive treatment: is prophylaxis in terms of screening, education, instruction, monitoring and at times provision of non-invasive therapy. e.g. fluoride application, fissure sealants, mouth guards.

Refusal of treatment: this may be on the part of the patient or the clinician. A patient has the right to refuse any treatment for whatever reason, and does not need to divulge that reason. Unless this situation is life threatening

or could potentially put a third person at risk, the clinician cannot over-rule their desires. If a paternalistic approach is taken and treatment is "forced", the clinician must have enough motivation to support such interventions should the patient take legal action against him/her. By the same token, a dentist may refuse to treat if the patient's demands are unrealistic or potentially damaging to the patient, or if the dentist does not feel morally comfortable or sufficiently competent enough to carry out the procedure.

CLINICAL RESEARCH

Research consists of "investigations undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of humans, culture and society, and the use of this knowledge to devise new applications."[3] It is used to establish or confirm facts, reaffirm the results of previous work, solve new or existing problems, support hypotheses, or develop new theories. A research project may also be an expansion on past work in the field. To test the validity of instruments, procedures, or experiments, research may replicate elements of prior projects, or the project as a whole. The primary purposes of research are investigation, discovery, interpretation, documentation, and the dissemination of knowledge. In other words, it is a "process of steps used to collect and analyze information to increase our understanding of a topic or issue". It consists of three steps: Pose a question, collect data to answer the question, and present an answer to the question.[4]

"**Clinical research** aims to develop generalizable knowledge to improve health and /or increase understanding of human biology."[5] As such, it often involves patients as research participants. This has led to the explosion of literature on the ethics of the exploitation of human subjects, and on the provisions for safeguarding vulnerable subjects.[5] Vulnerability is susceptibility to harm, attack or injury.[6] A patient /participant may be vulnerable due to the possibilities of experiencing physical pain; debilitation; emotional stress; economic, educational or knowledge deficiencies; power differentials; a perception of subordination; dependency; peer pressure; or by coercion, inducement or offers of incentives. All of these decrease the freedom of volunteering and render patients susceptible to exploitation.

CLINICIAN INTENT AND PATIENT EXPECTATIONS

When a patient consents to any form of dental treatment, that agreement is based on the expectation that the dentist should be competent, that the materials have been approved by the appropriate manufacturers and authorities, that the techniques are recognized and generally accepted in the scientific community, and that both parties have an expectation of success. At the same time the intention of the clinician is to provide a therapeutic benefit to the patient. When a clinician knowingly decides to "test out" a new material or procedure during the course of routine treatment, his/her mental state shifts.[7] Astington termed this the "Intentional chain" which consists of a sequence of processes starting with desires, beliefs, and intentions that lead to actions in order to reach a goal.[8] The focus becomes a commitment to carrying out an action in the future that requires a certain amount of planning and forethought in order to accomplish a desired goal, based on the belief that the course of action will satisfy that desire.[8]

The intentional chain equates to clinical research, which can be conducted only with the patient's full awareness, understanding and free, voluntary consent. Patients can never be kept blind to the fact that they are being used in a trial, and should not be manipulated, offered incentives such as offers of free donations (implants) or treatment, or in any way coerced in return for their participation. In addition, they cannot be denied routine treatment if they refuse the experimental alternative.

THE "REASONABLE MAN" RULE

Even if a clinician has received free, educated (informed), autonomous patient consent, there remains a moral commitment that a novel procedure is undertaken only if there is a high expectancy of success, based on sound clinical judgment, and supported by a general consensus from peers. In addition, it should be performed only if the clinician has the necessary skills, experience and training to attempt the new approach. If all of these criteria are not satisfied and the intention is experimental rather than therapeutic, then the actions must be seen as research and not treatment. The patient too assumes a new role, and becomes a (potentially) vulnerable research subject. In order to protect both parties, a research protocol should be drafted and submitted to any reputable scientific and ethical review board for approval and monitoring.

The "Reasonable Man" theory refers to a test whereby a hypothetical person is used as a legal standard, especially to determine if a negligent act was performed. This hypothetical person, referred to as the reasonable/prudent man, is gauged as exercising the average care, skill, and judgment in conduct that society requires of its members for the protection of their own interests and of that of others. This serves as a comparative standard for determining liability. The process often involves the application of an objective test in which one compares the particular action to that which a reasonable person would perform under similar circumstances.[9] Thus when embarking on clinical research which carries both risks and benefits for patients and clinicians, the same principle can be applied. A prudent practitioner should ask "What would a reasonable clinician do under these circumstances, and what would a reasonable patient expect?" Furthermore, when weighing up the risks against the benefits, consider whether a reasonable person, in the position of the patient, if warned of the risks, would find them significant? The clinician should also be astute enough to know whether the patient would indeed consider the risks significant.

CONCLUSIONS

There are two sets of simple "**AEIOU**" questions, one for patients, one for clinicians. Asking these questions may help those embarking on research within the ambit of routine treatment to decide whether it is scientifically and morally justified.

For the patient: Have they been granted full **Autonomy** in the decision making process? Were they adequately **Educated** about the procedure? Were they given all the necessary **Information** needed to make a decision? Were

they permitted time to seek other **Opinions**? Did they display full **Understanding** of the risks and benefits?

For the clinician: Will the study provide **Added knowledge** or benefits to future patients and the scientific community? Is the intervention **Ethically sound**? What is the primary **Intention**? Are there anticipated **Outcomes** of success? Do the actions display a **Utilitarian** approach (i.e. the greatest good for the greatest number). Note that the "I" is always in the middle because both parties must always be central to all decision making processes.

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