Futile treatment: Managing unreasonable demand

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Background

With advancement of medical technology and emerging health crisis, there are many treatments available on markets for management of communicable and non-communicable diseases. Some products might not be subject to legislative regulation as they are conceived to be supplements or natural ingredients. Some drugs are being used as Off-label use. Medicine use is considered Off-label when used for an indication, at a dose, via a route of administration, or in a patient group that is not included in the product information approved by the Therapeutic Goods Administration (TGA) or Food and Drug Administration (FDA)[1] . An important reason for use of Off-label medicines is to improve access to innovative treatments or to address medical needs and preferences of patients, especially when no other options are available.

What happens if the patient or his or her appointed attorney/guardian files a declaratory relief and injunctive relief to order healthcare provider to provide a particular treatment which the healthcare provider regards unnecessary? The case *Frey v Trinity Health Mich*[2] can illuminate us how to handle the situation.

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[1] *Bell JS, Richard CG. Off Label Medicine use: Ethics, Practice and future direction. Aus J Gen Pract 2021; 50(5): 329-321.*
[2] *Frey v. Trinity Health-Michigan, 2021 Mich. App. LEXIS 6988 (Mich. Ct. App. Dec. 17, 2021)*

Is healthcare provider required to administer treatment orders requested by patient or the appointed attorney/guardian?

Analysis of Frey case[3]

Mr. F was infected with COVID-19 and was admitted and later transferred to intensive care with continuing decline of health condition. The healthcare provider followed its standard protocols, administering remdesivir, steroids and antibiotics. Mr. F's daughter, Ms F, designated patient advocate, conducted her own research of additional treatments for her father and learned about ivermectin, an anti-parasite medication commonly used to treat parasitic diseases in humans and animals. FDA had not approved it for this use notwithstanding some physicians prescribed ivermectin to treat COVID- 19, and the Centre for Disease Control (CDC) recommended against its use for treating COVID-19. The internal policy of the healthcare provider does not permit the use of ivermectin to treat COVID-19. Cochrane review found no evidence to support the use of ivermectin for treating COVID-19 or preventing SARS-CoV-2 infection[4].

Ms. F contacted Dr. K and prescribed ivermectin for Mr. F. Dr. K had no admission privilege to the hospital and did not meet with Mr. F prior to prescribing, but he did review the medical records. The hospital refused to administer the ivermectin because it was contrary to their policy, and against the medical judgment of Mr. F's attending physicians.

Ms. F then filed a complaint for emergency declaratory relief and injunctive relief to force the physicians and the hospital to administer ivermectin to Mr. F. Her arguments were that the hospital had administered all its medications and implemented all of its protocols, but Mr. F remained in critical condition and continued to decline. Ms. F sought a declaration as to the parties' rights and she further sought an injunctive order directing the hospital to comply with Dr. K's medical orders. This case was heard before the State Court of Appeals.

The issue was to determine whether the hospital should follow a physician's medical orders despite those orders contrary to guidance and internal policies.

Principles of granting injunctive relief

The *American Cyanamide case*[5] would provide the standard of tests (also adopted by Hong Kong Court[6]) for granting injunctive relief.

- There must be a serious question to be tried
- The applicant (on behalf of representee) would suffer a loss if the injunction was not granted which could not be compensated by damages
- The 'balance of convenience' lies in favour of granting the injunction that the possible damage to the applicant if not granted is likely to be greater than the potential harm to the respondent

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[3] *Allman CJ. Case law update. J Health Risk Manag 2022; 1-7. doi: 10.1002/jhrm.21515.*

[4] *Popp M, Reis S, Schießer S, Hausinger RIlona, Stegemann M, Metzendorf M-I, Kranke P, Meybohm P, Skoetz N, Weibel S. Ivermectin for preventing and treating COVID-19. Cochrane Database of Systematic Reviews 2022, Issue 6. Art. No.: CD015017. DOI: 10.1002/14651858.CD015017.pub3.*

[5] *American Cyanamide Co Ltd v Ethicon Ltd* [1975] AC 396

[6] Lew ML. *Hong Kong Court Confirms Principles for Interim Injunction to Stay Arbitration*. Mayer Brown 21 Aug 2020 https://www.mayerbrown.com/en/perspectives-events/publications/2020/08/hong-kong-court-confirms-principles-for-interim-injunction-to-stay-arbitration; *Atkins China Ltd v China State Construction Engineering (Hong Kong) Ltd* [2020] HKCFI 2092.

The relative merits of each side will be considered to determine whether there is prima facia case (based on the first impression; accepted as correct until proved otherwise) established to grant injunction. It requires the evidence that there is a probability the plaintiff (claimant) to obtain relief at the end of the trial[7]. The strength of evidence depends upon the nature of the rights and the practical consequences likely to follow[8].

In Australia, the High Court has affirmed that there must be a legal or equitable right to be determined, *Australian Broadcasting Commission v Lench Game Meat Pty Ltd*[9]. *Lench* applied for injunctive relief to prevent the ABC broadcasting the video of the operation of its plant including the slaughtering of animals by unknown person installing video cameras on the premise. ABC appealed to the High Court to overturn the decision of Supreme Court. However, animal welfare issues have always been the legitimate matters of public debate so it is important for public interest groups in raising awareness of these issues and of generating public debate in Australia[10]. The patient's right argument by Ms F cannot override the importance of provision of evidence-based treatment. The policy of hospital and medical judgement of attending doctor cannot be overturned lightly as this would put patient safety at risk.

The four factors considered by the Court of Appeal to determine granting injunctive relief[11]

(1) irreparable harm would occur without the issuance of an injunction,
(2) the case likely to prevail on the merits,
(3) harm to Mr. F without injunction outweighs the harm to the healthcare provider,
(4) public interest will be harmed if a preliminary injunction is issued.

All four must be established before the Court of Appeals would grant a preliminary injunction.

According to clinical information provided by healthcare provider, Mr. F was suffering other medical conditions related to COVID-19 rather than actively fighting against COVID-19 so ivermectin was not medically indicated or appropriate for Mr. F and also a risk of harm to him. Ms. F did not meet the burden of irreparable harm.

In case of ordering to change medical treatment, the evidence of effectiveness of alternative treatment ought to be very strong, *Beecham case*[12]. The evidence is very weak on Ms F's side to prove irreparable harm, or suffering loss if injunction not granted, and "balance of convenience" not favouring Ms. F.

Ms F argued the merit of the case that ivermectin was approved by the FDA for use and Off-label use is not illegal.

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[7] *Beecahm Group Ltd v Bristol Laboratories Pty Ltd* (1968) 118 CLR 618
[8] Ibid
[9] *Australian Broadcasting Commission v Lench Game Meat Pty Ltd* (2001) 208 CLR 199
[10] Ibid at 217, 218vKirby J reinforced the view that such debate should be protected:
"The concerns of a governmental and political character must not be narrowly confined. To do so would be to restrict, or inhibit, the operation of the representative democracy that is envisaged by the Constitution. Within that democracy, concerns about animal welfare are clearly legitimate matters of public debate across the nation. So are concerns about the export of animals and animal products. Many advances in animal welfare have occurred only because of public debate and political pressure from special interest groups…."
[11] See ref 2 *Frey* and 3 Allman, 2021
[12] See ref 6 *Beecham*

What is the purpose of off-label use of medicine?

Off-label use of medicine

Most US physicians agree that Off-label medicine use should not be promoted[13]. Both the US FDA and Australian TGA prohibit advertising for off-label indications to prescribers or the general public[14]. Off-label use of medicines is in general not supported by the same level of evidence as medicines licensed for vulnerable population group such as paediatric use[15]. This may result in increased uncertainty on efficacy as well as the risk for toxicity and other side effects.

In *Daubert v. Merrell Dow Pharmaceuticals*[16], the Court of Appeals agreed and affirmed, citing *Frye v. United States*[17] for the rule that expert opinion based on scientific technique is inadmissible unless the technique is "generally accepted" as reliable in the relevant scientific community. It must be at least coming from consensus meeting among medical profession.

In *Frey case,* the opinion of Dr. K cannot be accepted as expert opinion as there is widespread consensus against using ivermectin for COVID-19. The Off label use is not justified. Another issue is whether the judiciary has the legal authority to compel a hospital to administer a drug, on an Off-label use, that the hospital considers harmful.

It is very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable and the assessment of medical risks and benefits is a matter of clinical judgment which a judge would not normally be able to make without expert evidence as reflected by an English case *Bolitho*[18] .If the judge is presented with different views from two medical experts, the judge cannot prefer either one if both views can withstand logical analysis. Only when the view deems to be illogical, it can be dismissed. One would not conclude the management of hospital being illogical. On the other hand, could the demand by Ms. F be considered illogical?

Harm to healthcare provider

Ms. F argued that any harm to the hospital if the injunction was granted would be negated by her offer to sign a release of liability. However, the potential harm to the healthcare provider in this type of case would be broader because the court directive could open the door for a flood of similar suits from other patients with COVID-19 suing to obtain care that is contrary to hospital policies. This would tilt the "balance of convenience" favouring the respondent, the healthcare provider.

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[13] Kesselheim AS, Woloshin S, Lu Z, Tessema FA,Ross KM, Schwartz LM. Physicians' perspectiveson FDA approval standards and off-label drug marketing. *JAMA Intern Med* 2019;179(5):707–09. doi: 10.1001/jamainternmed.2018.8121.

[14] See ref 1 Bell and Richard 2021

[15] Schrier, L., Hadjipanayis, A., Stiris, T. *et al.* Off-label use of medicines in neonates, infants, children, and adolescents: a joint policy statement by the European Academy of Paediatrics and the European society for Development Perinatal and Pediatric Pharmacology. *Eur J Pediatr* 2020;179**,** 839–847. https://doi.org/10.1007/s00431-019-03556-9

[16] *Daubert v. Merrell Dow Pharmaceuticals*, Inc., 509 U.S. 579 (1993)

[17] *Frye v. United States*, 54 App. D. C. 46, 47, 293 F. 1013, 1014

[18] *Bolitho v City and Hackney Health Authority* [1997] 3 W.L.R. 1151 "*In those circumstances it cannot be suggested that it was illogical for Dr. D, a most distinguished expert, to favour running what, in his view, was a small risk of total respiratory collapse rather than to submit P to the invasive procedure of intubation."*

Public interest

Similarly, the authority of Ms F as patient advocate is not absolute. Is her act protecting the legal or equitable right of Mr. F? It is also the public interest to protect patients from treatment without proved value of effectiveness and safety particularly for those unable to consent. The Court of Appeal further stated that the role of the courts is not to overrule the medical judgment of the treating physicians and the policies of the treating hospital. The public interest is best served by permitting physicians and hospitals to follow established procedures and use their professional judgment to determine appropriate medical treatment.

Discussion on managing demand for futile treatment

It serves the best interest of the community health by leaving medical decisions to medical professionals in consultation with their patients and treatment for patients should be evidence based to ensure the best practices for patient safety. Doctor is not under a legal duty to provide treatment not conferring "benefit" on individual case or in his or her "best interest", the *Bland* case, on the basis that there was no potential for improvement, the treatment received by Bland, was deemed not to be in his best interests[19]. Not providing "futile" treatment does not breach duties of doctor (criminal or civil) in provision of care to patients. The New South Wales Supreme Court declared that life sustaining treatment for a prisoner with end-stage lung cancer, who lacked capacity and was expected to live for only a matter of days or weeks, was futile and need not be given.[20]. The "best interests" assessment not to treat can be justified at law if there is a clear basis for deciding treatment that is futile or it is extremely unlikely for recovery[21].

Based on ethical principle of patient autonomy, patient and their attorney/guardians/surrogates have the right to request certain medical treatments on that same basis. This poses a big challenge to doctors and healthcare providers to implement futility with the threat of litigation. Assessment to the futility of treatment will usually be made by the treating doctor at first instance. If the matter is being considered by court, the court is not bound by the medical experts but the principle is that decision to appropriate treatment is matter for the expertise of medical professionals. The court did not accept the family's view that treatment for a severe brain damage 75 years old lady was in the patient's best interests[22]. Although courts will consider patient and family wishes in deciding whether treatment is either futile or overly burdensome not in a patient's best interests, they have generally deferred to the views of medical practitioners about treatment decisions[23]. Mentally competent person could not demand provision of treatment if doctors did not consider treatment clinically indicated as stated in English Court of Appeal case that no professional could be ordered to provide a form of medical intervention that was in their view not an appropriate form of treatment[24].

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[19] *Airedale NHS Trust v Bland* [1993] AC 789 at 858-9

[20] *Re a Patient* (2011) 80 NSWLR 354 at [6]

[21] Willmott L, White B, Smith MK, Wilkinson DJ. Withholding and withdrawing life-sustaining treatment in a patient's best interests: Australian judicial deliberations. *Med J Aust* 2014;201(9):545-7. doi: 10.5694/mja13.10874.

[22] *Messiha v South East Health* [2004] NSWSC 1061

[23] See ref 21 Willmott et al, 2014..

[24] *R (on the application of Burke) v the General Medical Council* [2006] QB 273 at 3-1-302,

From ethical perspectives, paper by Clark has discussed four categories of medical futility by the Ethicists Baruch Brody and Amir Halevy[25]. Physiological futility or quantitative futility is one category applying to treatments that fail to achieve their intended physiological effect. The category of imminent-demise futility refers to "patient will not survive to discharge" notwithstanding proposed intervention. The third category is lethal-condition futility which the patient has a terminal illness and the intervention does not affect the prognosis. The fourth category is qualitative futility which an intervention fails to lead to an acceptable quality of life for the patient. Each case can be analysed taken reference from the four categories. For Mr. F, it would fit under both quantitative and qualitative futility.

The medical futility debate can be in conflict with the principles of patient autonomy, beneficence, maleficence and distributive justice. In seeking the balance, doctors must reach a consensus on what constitutes a reasonable medical treatment, and patients and surrogates must restrict their self-advocacy to what is fair and equitable for all[26].

The justification of medical treatments on the basis of weighing the benefits and burdens and the appropriate use of medical resources is firmly rooted in the Catholic moral tradition of the ordinary versus extraordinary means distinction that the Pontifical Academy of Life's *Respect for the Dignity of the Dying* to *Evangelium Vitae* has made it quite clear that individual autonomy is not an absolute[27]. Pope John Paul II applied this principle to medical treatments in *Evangelium Vitae* when he stated: "Certainly there is a moral obligation to care for oneself and to allow oneself to be cared for, but this duty must take account of concrete circumstances. It needs to be determined whether the means of treatment available are objectively proportionate to the prospects of improvement"[28]. Paper by Panicola in Hasting Centre Report has highlighted the six moral norms emerging from the centuries-long history of Catholic teachings on prolonging life and one is NOT morally obliged to prolong life with medical means when the medical treatments offer NO reasonable hope of benefit in helping to pursue the spiritual goods of life, and also if the medical treatment profoundly frustrates the pursuit of the spiritual goods of life[29]. It is also a moral obligation that medical treatment must offer a reasonable hope of benefit.

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[25] Clark P A. Medicine and Society: Medical Futility: Medical and Legal Analysis. *Virtual Mentor* (American Medical Association Journal of Ethics) 2007; 9(5):375-383. DOI 10.1001/virtualmentor.2007.9.5.msoc1-0705.

[26] Luce JM. Physicians do not have a responsibility to provide futile or unreasonable care if a patient or family insists. *Crit Care Med.* 1995; 23:764.

[27] Pope John Paul II. Chapter III. In: *Evangelium Vitae.* March 25, 1995. https://www.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae.html. Access 10 July 2022

[28] Ibid

[29] Panochia M. Catholic Teaching on Prolonging Life: Setting the Record Straight *The Hastings Center Report 2001;* 31 (6): 14-25

Conclusion

Implementation of a futility policy would give rise to claims for injunctive relief. The principles adopted by courts in granting injunctive relief require a strong *prima facia* case in different common law jurisdictions and the court generally defers to medical opinions about decision on medical management as it bears stronger evidence to justify the relative merit of the case. The recent US *Frey* case further reinforce the principles. When ethical or legal issues such as *Frey* arise in the context of patient care, paper by Allman[30] has suggested that the risk manager should consider bringing in the legal and ethical teams together quickly to help the organisation and the patient formulating the best possible outcome for both parties. When either the physician or family believes treatments being futile, negotiating care is a delicate process and should build upon respect of both patient and professional value. The discrepancies require physicians to exercise humility and professional integrity[31]. Physicians should explore reasons for requesting a treatment not to be in the clinical interest of the patient and their understanding and expectations[32]. The UK General Medical Council guidance has advised physicians not to provide the treatment if not serving the patient's real need after thorough discussion to explore the reasons of the request[33]. Respect of persons and beneficent approaches can lead to ethically and morally viable solutions. This would avoid unnecessary legal proceeding and safety of the patient can be assured.

Key messages

1. Many treatments are available on market due to advancement of medical technology and emerging health crisis both for communicable and non-communicable diseases. Public needs to receive professional advice from medical professionals who have appraised the evidence of effectiveness and safety on particular patients and health conditions.
2. Patient autonomy does not imply that patient can demand treatment to be provided by doctor if the proposed treatment is not clinically indicated for the best interest of patient.
3. Doctors have professional responsibility to evaluate the most appropriate treatment for patients' well-being and quality of life.
4. Medical futility should be considered from boarder perspectives including both physiological effect, quality of life, and prognosis.
5. Futile medical treatment is in conflict with fundamental principles of ethics regarding beneficence, maleficence and distributive justice.

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[30] See ref 3

[31] Kasaman DL. When Is Medical Treatment Futile? A Guide for Students, Residents, and Physicians. *J Gen Intern Med* 2004;19: 1053–1056.

[32] General Medical Council. *Guidance on professional standards and ethics for doctors: Decision making and consent*. UK: GMC, 2020. Available https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf Access 6 August, 2022

[33] Ibid

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