

EDITORIAL



Focus on better care and ethics: Are medical ethics lagging behind the development of new medical technologies?

Sharon Einav^{1,2*}  and Otavio T. Ranzani^{3,4}

© 2020 Springer-Verlag GmbH Germany, part of Springer Nature

Technologies fall into two broad categories: evolutionary and revolutionary [1]. Evolutionary technologies develop slowly and are more common. Revolutionary technologies occur sporadically and have the potential to alter medical care entirely. Mechanical ventilation, extracorporeal life support and liver and renal replacement therapy were revolutionary when they were first introduced. These technologies have rapidly pervaded the practice of intensive care and are currently considered mainstream intensive care treatments. However, the fact that these technologies have become mostly evolutionary in the last decades does not mean we have addressed the ethical dilemmas created by their use.

We are still mostly incapable of identifying the individual patient who will not benefit from invasive mechanical ventilation. Prognostication is imperfect and is likely to remain so in the foreseeable future. Yet one in four patients with acute respiratory failure receiving respiratory support with either noninvasive ventilation or the high-flow nasal cannula has a do-not-intubate order. The establishment of such orders has little to do with either the severity of the acute illness or the comorbidity load [2]. At times it also is made without patient/family input [2]. Frailty is also associated with poorer outcomes following mechanical ventilator support [3]. But retrospective associations observed in cohort studies between frailty scores and outcomes provide only prognostic validity for populations, not individuals. We therefore

cannot decide whether to intubate an individual patient based solely on such data.

The use of vv- and va-ECMO has increased three-fold in less than a decade [4]. Clinicians may consider ECMO an acceptable means of avoiding mechanical ventilation. However, immune compromised patients that are unlikely to benefit from mechanical ventilation are equally unlikely to benefit from ECMO [5]. There is a steady increase in the relative proportion of older patients receiving ECMO despite a clear association between age and mortality in this population [4, 6]. A survey conducted in 39 countries showed that while age was an important reason to withhold ECMO therapy, it had no association with withdrawal [7]. In fact, with regard to ECMO therapy it seems that legalities and physician preferences may trump both science and patient preferences. In the same study, decisions regarding withdrawal of ECMO therapy were independently associated with patient comorbidities and preferences, but also associated with respondent religiosity and legal constraints [7]. Shared decision-making is also not necessarily practiced when managing patients on ECMO: only 53.2% and 45.3% of the respondents claimed they involve surrogates or awake patients [7].

Extracorporeal support has been offered to critically ill patients with liver failure for more than 20 years. The twenty-five RCTs that have diligently studied whether such support actually reduces mortality yield only moderate certainty regarding the possible effect of this treatment on mortality and no certainty at all regarding its effect on other patient-important outcomes [8]. Finally, recent literature regarding RRTs in developing countries highlights major issues that should cause at least some concern regarding potential inequalities of care [9].

*Correspondence: einav_s@szmc.org.il

¹ General Intensive Care Unit, Shaare Zedek Medical Center, Jerusalem, Israel

Full author information is available at the end of the article

Even in developed countries we remain poorly informed regarding the effects of RRT when combined with other treatments (e.g., lung–kidney interactions in critically ill patients [10]). And we are probably increasing the rate of secondary infection as we provide more and more invasive treatments [11, 12].

The examples given above serve to highlight the ethical complexity of introducing new technologies as the introduction of each new technology ushers in a very distinct set of new ethical conundrums. Earlier this year, researchers restored cellular function to the brain of a decapitated pig using extracorporeal perfusion [13]. Within hours of the experiment, the tabloids described it as “Frankenstein style.” Eye-tracking and speech-generating technologies are already being piloted for communication with intubated patients [14], but more direct methods of communication are also being developed. A noninvasive brain–computer interface was recently used for successful continuous tracking of a computer cursor [15], and speech has already been synthesized from neural decoding using an intracranial grid [16]. These technologies raise concerns regarding the ethics of literally reading minds.

Medical technology itself is not required to be ethical; the ethics of medical technology revolves around when, how and on whom each technology is used. Interestingly, technological advancement has been accompanied by implementation of more treatment limitation [17]. At this time, the individual practitioner is primarily responsible for the ethical use of new technologies. It is high time to establish an ethical framework for the introduction of cutting-edge technologies to the practice of intensive care medicine, thereby making this issue a community responsibility as well. Table 1 presents the authors suggestions for the possible components of such

an ethical framework. Manufacturer responsibility currently includes proof of benefit prior to marketing. It should also include transparent reporting of post-marketing surveillance for harm and ongoing benefit. Professional societies should clarify the indications for use of each technology and provide platforms for training, public opinion and relevant data sharing [18]. Hospital administrations should be required to develop local expertise and to report outcomes and complications to central agencies so that these can be compared. Finally, the responsibility of the individual practitioner for their own training and education and for shared decision making [19]—particularly when uncertainty remains regarding the balance of benefit versus harm—is a continuous process.

Our proposed framework is fraught with limitations. Examples include the ongoing doubts regarding current metrics for patient-centered ICU outcomes, changes occurring over time in outcome data as specific treatment issues are uncovered, potential funding sources and division of responsibilities (e.g., can device manufacturers overcome their internal conflict inherent to any such assignment) and most importantly whether it is ethical to withhold a potentially beneficial new treatment while we attempt to learn all its benefits and drawbacks. Recognizing that such issues exist is important. Discussing these issues and seeking how to overcome them should constitute our first steps toward improving how we address ethical issues related to new technologies.

Author details

¹ General Intensive Care Unit, Shaare Zedek Medical Center, Jerusalem, Israel.

² Faculty of Medicine, Hebrew University, Jerusalem, Israel. ³ Pulmonary Division, Heart Institute (InCor), Hospital das Clinicas HCFMUSP, Faculdade de Medicina, Universidade de Sao Paulo, São Paulo, Brazil. ⁴ Barcelona Institute for Global Health, ISGlobal, Barcelona, Spain.

Table 1 A proposed ethical framework for the implementation and use of new technologies

| Responsible body | Time in relation to device approval | Responsibility to provide |
|-------------------------|--|---|
| Manufacturer | Before device approval | Two multicenter studies showing patient-centered outcome improvement Two multicenter studies supporting cost-effectiveness |
| | After device approval | Annual year updates of cost-effectiveness calculations, adverse events, etc. |
| Professional society | Before device approval | Setting training/experience requirements Polling of public opinion |
| | After device approval | Periodic expert systematic review of the literature per device. Maintenance of open multicenter databases Availability of online expert forums/consults |
| Hospital administration | Before device approval | Ensuring staff training |
| | After device approval | Maintenance of training and expertise Relevant data collection regarding patients' outcomes |
| Individual practitioner | Training Ongoing literature review (self-education) Shared decision making | |

Funding

None.

Compliance with ethical standards**Conflicts of interest**

SE and OTR declare no competing interests.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Received: 3 February 2020 Accepted: 11 May 2020

Published online: 27 May 2020

References

- Iserson KV, Chiasson PM (2002) The ethics of applying new medical technologies. *Semin Laparosc Surg* 9:222–229
- Wilson ME, Mittal A, Karki B, Dobler CC, Wahab A, Curtis JR, Erwin PJ, Majzoub AM, Montori VM, Gajic O, Murad MH (2020) Do-not-intubate orders in patients with acute respiratory failure: a systematic review and meta-analysis. *Intensive Care Med* 46:36–45
- Fernando SM, McIsaac DI, Rochweg B, Bagshaw SM, Muscedere J, Munshi L, Ferguson ND, Seely AJE, Cook DJ, Dave C, Tanuseputro P, Kyere-manteng K (2019) Frailty and invasive mechanical ventilation: association with outcomes, extubation failure, and tracheostomy. *Intensive Care Med* 45:1742–1752
- Karagiannidis C, Brodie D, Strassmann S, Stoelben E, Philipp A, Bein T, Muller T, Windisch W (2016) Extracorporeal membrane oxygenation: evolving epidemiology and mortality. *Intensive Care Med* 42:889–896
- Schmidt M, Combes A, Shekar K (2019) ECMO for immunosuppressed patients with acute respiratory distress syndrome: drawing a line in the sand. *Intensive Care Med* 45:1140–1142
- Yu HY, Wang CH, Chi NH, Huang SC, Chou HW, Chou NK, Chen YS (2019) Effect of interplay between age and low-flow duration on neurologic outcomes of extracorporeal cardiopulmonary resuscitation. *Intensive Care Med* 45:44–54
- Abrams D, Pham T, Burns KEA, Combes A, Curtis JR, Mueller T, Prager KM, Serra A, Slutsky AS, Brodie D, Schmidt M, International ECMO Network (ECMONet) (2019) Practice patterns and ethical considerations in the management of venovenous extracorporeal membrane oxygenation patients: an international survey. *Crit Care Med* 47:1346–1355
- Alshamsi F, Alshammari K, Belley-Cote E, Dionne J, Albrahim T, Albudour B, Ismail M, Al-Judaibi B, Baw B, Subramanian RM, Steadman R, Galusca D, Huang DT, Nanchal R, Al Quraini M, Yuan Y, Alhazzani W, GUIDE Group (2020) Extracorporeal liver support in patients with liver failure: a systematic review and meta-analysis of randomized trials. *Intensive Care Med* 46(1):1–16. <https://doi.org/10.1007/s00134-019-05783-y>
- Navva PK, Venkata Sreepada S, Shivanand Nayak K (2015) Present status of renal replacement therapy in Asian countries. *Blood Purif* 40:280–287
- Joannidis M, Forni LG, Klein SJ, Honore PM, Kashani K, Ostermann M, Prowle J, Bagshaw SM, Cantaluppi V, Darmon M, Ding X, Fuhrmann V, Hoste E, Husain-Syed F, Lubnow M, Maggiorini M, Meersch M, Murray PT, Ricci Z, Singbartl K, Staudinger T, Welte T, Ronco C, Kellum JA (2020) Lung-kidney interactions in critically ill patients: consensus report of the Acute Disease Quality Initiative (ADQI) 21 Workgroup. *Intensive Care Med* 46(4):654–672. <https://doi.org/10.1007/s00134-019-05869-7>
- Abrams D, Grasselli G, Schmidt M, Mueller T, Brodie D (2020) ECLS-associated infections in adults: what we know and what we don't yet know. *Intensive Care Med* 46(2):182–191. <https://doi.org/10.1007/s00134-019-05847-z>
- Denny KJ, Kumar A, Timsit JF, Laupland KB (2020) Extra-cardiac endovascular infections in the critically ill. *Intensive Care Med* 46(2):173–181. <https://doi.org/10.1007/s00134-019-05855-z>
- Vrselja Z, Daniele SG, Silbereis J, Talpo F, Morozov YM, Sousa AMM, Tanaka BS, Skarica M, Pletikos M, Kaur N, Zhuang ZW, Liu Z, Alkawadri R, Sinusas AJ, Latham SR, Waxman SG, Sestan N (2019) Restoration of brain circulation and cellular functions hours post-mortem. *Nature* 568:336–343
- Bodet-Contentin L, Gadrez P, Ehrmann S (2018) Eye-tracking and speech-generating technology to improve communication with intubated intensive care unit patients: initial experience. *Intensive Care Med* 44:676–677
- Edelman BJ, Meng J, Suma D, Zurn C, Nagarajan E, Baxter BS, Cline CC, He B (2019) Noninvasive neuroimaging enhances continuous neural tracking for robotic device control. *Sci Robot*. 4(31):eaaw6844. <https://doi.org/10.1126/scirobotics.aaw6844>
- Anumanchipalli GK, Chartier J, Chang EF (2019) Speech synthesis from neural decoding of spoken sentences. *Nature* 568:493–498
- Sprung CL, Ricou B, Hartog CS, Maia P, Mentzelopoulos SD, Weiss M, Levin PD, Galarza L, de la Guardia V, Schefold JC, Baras M, Joynt GM, Bülow HH, Nakos G, Cerny V, Marsch S, Girbes AR, Ingels C, Miskolci O, Ledoux D, Mullick S, Bocci MG, Gjedsted J, Estébanez B, Nates JL, Lesieur O, Sreedharan R, Giannini AM, Fuciños LC, Danbury CM, Michalsen A, Soliman IW, Estella A, Avidan A (2019) Changes in end-of-life practices in European intensive care units from 1999 to 2016. *JAMA* 321:1–12. <https://doi.org/10.1001/jama.2019.14608>
- Alhazzani W, Moller MH, Belley-Cote E, Citerio G (2019) Intensive care medicine rapid practice guidelines (ICM-RPG): paving the road of the future. *Intensive Care Med* 45:1639–1641
- Lee HW, Park Y, Jang EJ, Lee YJ (2019) Intensive care unit length of stay is reduced by protocolized family support intervention: a systematic review and meta-analysis. *Intensive Care Med* 45:1072–1081