ICU

MANAGEMENT & PRACTICE

INTENSIVE CARE - EMERGENCY MEDICINE - ANAESTHESIOLOGY

VOLUME 20 - ISSUE 3 - 2020

Ageing Population

12

9 771377 756005

Stefan Heinemann
Professor of Business Ethics
FOM University of Applied Sciences
Essen, Germany

Spokesman
Ethics Ellipse Smart Hospital of the University Medicine
Essen, Germany

stefan-heinemann@gmx.de

@s_heinemann001

Patrick Stais
Managing Senior Physician
Lung Clinic Foundation
Bethanien Hospital
Moers, Germany

Patrick.Stais@bethanienmoers.de

Ethics as Superpower Primum Non Nocere Against All Pandemic Odds

Use Case COVID-19-ICU Bethany Hospital Germany

Medicine is an activity of special dignity at all times. Healthcare professionals are responsible actors and have to consider the business of operating ethics. Weighing up values under considerable time pressure, existential fates and critically discussed evidence is a considerable challenge for them, not only in pandemic times but always.

Ethics as Superpower in Medicine

Medicine has been an activity of a special dignity since ancient times and not only in Greek, Roman and Christian context of standards. Principally essential, methodically and, last but not least, ethically. Without being able to clarify the differentiated medical-historical and history of ideas references here, it should be mentioned that the Hippocrates (Bergdolt 2004) -Fan Galenos builds his Definitiones medicae on the τέχνη, in which the ιατρική assumes primary responsibility for his healing action, which is always primarily aimed at the non-harming well-being of the patient: τέχνη ιατρική (Schubert and Leschhorn 2006). With τέχνη both craftsmanship as well as art and science are addressed - a dimensioning that is not only relevant in terms of terminology and academia, which still puts doctors and the surrounding superstructure of politics, society, economy and technology in a relationship that is not always easy to balance. It is not without reason that the ethical dimension is of particular importance, because it is about people and their ethical essence. Hence: Without ethics, an ethical foundation there is no medicine in the full sense of the word.

Perhaps proper prevention, diagnostics, therapy and aftercare, maybe outcomes in the interest of the patient, maybe also a feasible job in the sense of doctors and nursing staff, in the end maybe even financially affordable, innovative, agile and digital in a cleverly constructed public health system – and there, where organised privately, even linked to efficient, legal and legitimate business models. All that is ostensibly "medicine" within a functionalist health system without ethics. On closer inspection, however, it becomes clear that "medicine" in the full sense can only be legitimate medicine, carried out by actors who bear moral responsibility. Medicine is much more than healing technique.

Therefore, doctors should not be replaced by artificial intelligence or nurses by robots [maybe they could someday (Wandschneider 2020; Crockett (2019)], but should only be supported by them within the framework of the ethical general mandate in the sense of a positive outcome and experience for the patients (and the doctors and nurses) - as exemplified by the Smart Hospital (Werner, et al. 2020); Heinemann 2018a; Heinemann 2018b) platform as a genuine combination of medical and economic goals with digital means under the clear primacy of humanity. People are not broken and need to be repaired, they need empathic and dignified healing.

"Medicine is one of the areas of life in which the need for ethical action becomes inevitable: Where people are weak, exposed and in need of help, they not only want to be sure that nothing illegal is happening to them, but that everything that is legally required is being done. If people are faced with illness in life, they immediately understand that legal requirements and prohibitions are inadequate and that, beyond the wording of the legal book, it is much more important to follow good laws as intended. This, however, transcends the area of legality, i.e. a hard standardisa-

tion of human action that is threatened with punishment, with regard to ethics" (Heinemann and Miggelbrink 2011).

Medical action is therefore the accomplishment of a skill and duty that cannot be exhaustively recorded in descriptive-real scientific categories, because the sphere of ethics – values, duty, normative realm – cannot be deduced from the facts. Hume and (!) Kant were right: The world is as it is, because in this world it is possible do to what needs to be done for moral reasons (Heinemann 2013; Hösle 1987). Health and illness are not simply facts, but rather states with normative valence (Gethmann-Siefert 1996). In the current situation of a pandemic, which confronts late-modern societies in the West, the already demanding task of the ethical foundation and practical feasibility of effective medical ethics can be characterised as an even more acute challenge for the medical profession (Doctors, and, always included: the nurses; but also the administrative stuff and all professions and basically all occupational groups that are part of the health care system in the broadest sense). On the one hand, because in the field of the long tradition of medical ethics itself, the discourses relevant to ethics as a discipline of philosophy about the nature and validity of ethical propositions are constantly emerging. Between ethical-universalistic and casuistic-relativistic basic orientation, legions of ethics span, sometimes as a large theoretical framework (mostly in the classics such as Aristotle, Kant or in utilitarianism, but not only there, also in the ethics of religions or alternative concepts), sometimes as a deliberately modest, pragmatic approach. Shopping in the Ethics-Supermarket? (Heinemann and Miggelbrink 2011). Well, there is an important difference between freedom and relativism.

However, in addition, these alternative theoretical offers are provoked by factual developments in technological as well as social areas, which mostly ironically precede ethics as a normative theory of descriptive morality (and even on this point there is no agreement) – just think of the digital transformation of medicine and healthcare. On the other hand, since medicine in its noble basic task – at least as it is understood here – often has little time, too little time for ethical reflections, out of the hard-factual nature of a clinical reality. This explains why, since Hippocrates, those ethical approaches have been popular in medicine that try to grasp medical action neither with hard principles nor with a detailed case report, but with so-called "middle principles" (Potthast 2008; Brenner 2006). However, especially where time becomes critical, and even more critical than perhaps most of the time anyway – namely, especially during the first wave of a pandemic – medical ethics actually becomes the real superpower that once again exceeds the already important professional excellence.

Especially in times of perhaps already over-dynamic scientific development, a research pressure not previously known in this way, and on the other hand socially broad denial of science, associated with an enemy that appears mysterious and still keeps its true nature from us – SARS-CoV-2 – the question is more than urgent how to actually deal with the patients who manifestly suffer from COVID-19. Which ethical considerations play a role here? How can they be justified? Which sound arguments can be given?

In this context, two questions are repeatedly discussed professionally and publicly:

First: The triage in the rationing of intensive care services – which was not yet necessary in Germany – when capacity is overloaded, and the question of how to deal with the therapy of a disease for which no causal therapy is available yet. However, there are always new headlines presenting many ideas, studies, trials and more that at least give hope for a therapeutic perspective (not to mention the question of solid immunity). Fortunately, the triage pandemic has not yet reached Germany (also because Italy was hit so hard first - and people in Germany were in fear and therefore behave very carefully); Descriptive and ethical balancing between need and prognosis is often a hardly manageable scenario that is difficult to bear for patients and doctors - when need outweighs availability. The basic tendency of rationalisation is ultimately the utilitarian economic form of "medicine" in the dangerous narrow focus on prioritising the prognosis category. The patient-specific, medical decision, on the other hand, will always be based on weighing up neediness and prognosis (under the premise of scarce resources) – which can also be valid if it is considered that, in hardship cases, an extremely poor prognosis would make treatment despite neediness unjust because of the bad situation. If there are enough inpatient beds for ventilation are available (assuming here - for now - that this form of treatment would be the first choice for a COVID-19 patient), not every patient can be treated in the sense of ex-ante triage. Keeping capacities free for expectable COVID-19 patients in the sense of ex-ante triage is again conflicting with the principle of avoiding damage ("Primum non nocere"). Ex-post triage, however, would also not be ethically justifiable because further treatment with prospects of success must not be interrupted in order to initiate a new treatment. The weakest are often not protected by triage in the conflict between non-harm and justice.

Obviously, the old principle of "Primum non nocere" comes into focus. This often-quoted sentence is of course not by Hippocrates, who also hardly wrote Latin (Smith 2005). Not even by Galenos, but probably by the English doctor Thomas Inman (Smith 2005). Whatever the reconstruction of the history of ideas, the question of how this principle can be justified for itself and/or in the context of other principles, and secondly how

those principles can be applied, remains as a systematic return – here with the concrete second example alongside the triage medicine, on the important question of which treatment option for COVID-19 is appropriate to medical ethics in terms of avoiding damage.

The latter example has recently been the subject of wide controversy in a kind of "conflict between the faculties" between clinical pneumologists at the Bethany hospital in Moers (Germany) and professional and other submissions (more on this below in the Bethany case). This is not an easy question, because it has descriptive-technical (data, evidence, etc.) and ethical aspects. The following considerations primarily serve to sort those aspects and develop some arguments for a damage-sensitive initial treatment and then to illuminate the current ventilation debate in this broad context.

Do-No-Harm in the Context of the Big Four: Autonomy, Non-maleficence, Beneficence and Justice

Indeed, as American bioethicists, Beauchamp and Childress (2001) have, in a sense, revived and re-launched a tradition that has shaped the discussion on medical ethics since the late 1970s. The authors clearly saw that on the one hand principles and material contents of norms, i.e. values, are necessary in medicine but nevertheless represent a considerable challenge in concrete application. Beauchamp and Childress do not speak of principles in the sense of the first principles or ultimate, universal foundations of metaphysics, but rather of principles of "medium scope," which generate orientation knowledge and open and advance the discourse, and do not lead to a dissolvable dissent at the beginning, so to speak. Since medical ethical issues are often massively driven by dissent, it certainly makes sense to turn to more pragmatic and, in a sense, more modestly justified theory of ethics. The disadvantage is, of course, that only a kind of "lowest common denominator" is possible on the basis of well-understood convictions (which of course does not mean that these common beliefs are automatically irrational or simply unacceptable on closer philosophical examination, but these four principles that Beauchamp and Childress have introduced into the debate are, strictly speaking, fungible). And Beauchamp and Childress must assume that most people share common understandings of a basic set of ethical values. But the authors do not articulate any further moral-philosophical claim. The decisive point is that it is not only about beneficence and nonmaleficence in the classic sense, but that the well-known two principles are expanded to include autonomy and justice, and a quasi-system is created; which, however, understandable against the background of the pressure of discourse, does not even have to deal with a hard claim to truth (as a cognitivist ethic would have to do). But all this comes at the price of a complex and thus not easy-to-use relation of beneficence and nonmaleficence (same with autonomy and justice). "Harm" for Beauchamp and Childress means "…thwarting, defeating, or setting back of some party's interest" (Beauchamp and Childress 2001), which in the medical context of course not the same as wrongdoing. "The relationship between the act of doing good and the absence of doing harm is complex, but they seem to be independent concepts. Beneficence and non-maleficence (as well as autonomy and justice) are prima facie duties, which is to say, their violation is ethically wrong unless it is justified by another prima facie duty" (Schwarz 2004). Nonmaleficence is an essential hurdle, a limitation for medical options.

A way is being sought, so to speak, to find an ethic that on the one hand still uses the term "principle" and thus formulates the certain strong claim in the sense of the Kantian tradition that it is not just mere reasoning or thinking, on the other hand, in the sense of the Aristotelian doctrine of virtue, is formulated sufficiently concrete to motivate action and a productive discourse, but thirdly, in the sense of utilitarianism, allows conceptual elements that are to be weighed up and also to be understood quantitatively. In the end, this mediates between the level of the individual case and the principle in such a way that the actually necessary hierarchy of principles is omitted and these fundamental questions are shifted to the individual level of interpretation and weighting.

This is quite unusual, because autonomy as well as justice are traditionally associated with extensive conceptual claims. It is particularly striking that Beauchamp and Childress argue more procedurally in the sense of American pragmatism, which in this case is ultimately given an old-continental principle articulation, without shying away from very specific values and their ethical characteristics, which in turn apply to the specific case and thus places the physician under specific responsibility on site. The mid-level ethics of Beauchamp and Childress is a material ethics without a systematic justification framework. The idea of such a middle position is very suggestive, because it promises good results with relatively little discursive use, quite comparable to the Rawls approach, who advocates a reflective equilibrium between principles and applications. To mark the coherence of statements that are mutually justified, but do not understand justification as a strong philosophical system, but much more modestly as only a contentual context, was also the driving force for Rawl's idea, on the one hand, to convey justice with utilitarian logic, and on the other hand bring the rather heterogeneous ideas of justice at least into discussion from an airplane perspective in his "Theory of Justice." There would be no talk of reconciliation here, no synthesis is pursued. Only under the (strict) conditions in the thought

experiment of the "original position" can at least the process be called fair (Rawls 2009). The epistemological challenges that Rawls and ultimately Beauchamp and Childress buy into with this approach, of course, lie in avoiding the last principles and thus also the final foundation. Coherence is the condition for the possibility of a reflective equilibrium; it does not arise from that. Now, to remain in the concrete example of medicine, there are quite a few different variants, to find such a balance of consideration or, as Beauchamp and Childress say, a balance of the principles in their sphere of application: How should one reasonably choose between the different options? Obviously, coherence is certainly important in itself, but does not justify whether reality has to adapt to ethical principles or vice versa. From the basic idea of a balance, no decision can be justified if – what actually happens in medical practice – the ideas of how such a balance should look like are different. "Empirically adopted beliefs become transparent, but ultimately they are only a mirror of the - in the specific case American - belief system in which they are determined" (von Engelhardt (2005), In other words: "The scientific-theoretical decision between induction and deduction is not made in principle – quite comparable to the scientific approach. Standards have to prove themselves in practice, just as a "good theory" in Popper's sense must have the property of failing in practice" (Heinemann and Miggelbrink 2011),

On the one hand, it explains pretty well why Beauchamp and Childress's approach was so successful in medicine as in bioethics (although criticised by the deductivist (Gert, Culver, Clouser) and casuistic (Jonsen, Toulmin) side (Heinrichs 2006). Nevertheless, the differentiation of the four principles remains highly demanding and their weighing up in concrete cases even more. "How such a procedure can give solid, action-focused orientations without ultimately becoming merely arbitrary in its desired meta-ethics freedom is, however, a core problem of many commonsense ethics (Beauchamp and Childress speak of a "common morality"). In the end, there is a naturalistic fallacy here. This could only be avoided in the long term with an actually 'absolute' – that is, the last-justified – ethics, but admittedly an unpopular alternative even for medical ethicists" (Heinemann and Miggelbrink 2011), On the one hand, the four principles in question are endorsed and applied in practice, for example, when it comes to a concrete case discussion. However, even with these principles, the term "principle" is still criticised, although it was not understood as it was seen – namely that the one principle, which is logically and ontologically more valuable than the other principle, would necessarily abolish the latter principle. Basically, Beauchamp and Childress offer a kind of heuristic in which concrete orientation knowledge can be developed in the discourse. "Certainly, one can complain that every ethical principle (be it a regulatory one like Beauchamp and Childress or constitutive) creates a virtual consensus to a certain extent, a consensus on principles that practically every reasonable person would agree with anyway. But the more material the ethics become, the less likely a consensus is: What to do if a patient prefers a solution that is not optimal for the doctor, or hard diagnoses from the doctor's point of view are unreasonable for the patient, or the doctor in the clinic can only use his working hour once and has to decide at the micro level (Engelhart 1996) where he allocates this resource (a question regarding the principle of justice)?" (Heinemann and Miggelbrink 2011).

With the principle of autonomy, Beauchamp and Childress think of positive and negative freedom. On the one hand, as an absence of coercion and manipulation, on the other hand, of course, as the presence of an emphatic promotion of those conditions, in order to ensure a reasonable, understandable freedom of decision for the patient. It is precisely in this sense that patient autonomy is absolutely crucial and the patient's right to sufficient, truthful and, above all, understandable, comprehensive information can be derived. The inform consent is the differentia specifica between physical injury and medical treatment and shows how differentiated the autonomy principle can be thought. Especially in times of digital transformation of the medical and healthcare industry, it will become even more important to promote patient sovereignty as a form of autonomy in dealing with health data and new forms of doctor-patient relationship (Heinemann and Matusiewicz 2020).

Apart from emergencies, in which the patient is obviously not able to consent voluntarily and freely, the focus must be on the explanation of possible consequences by the responsible and treating doctor for a patient, who of course also has the appropriate power of judgment. An indirect constraint, for example, because the doctor's reasoning is too strong and suggestive, is also not allowed. Here the challenge of dealing with intensive care medicine immediately arises – like the overall increase in treatments and interventions not medically indicated in the narrow sense.

The principle of justice does not make it easier, at least as long as health needs to be organised under scarcity. On the one hand, this has to do with the fact that the principle-theoretical and very demanding basic questions of justice also resonate in the form of a medium principle, such as the challenge of finding the right criterion (thinking of justice when it comes to the recognition that rights that you ascribe to yourself are also attributed to all equals, the problem arises that "rights" and "equality" cannot be precisely determined by justice itself), on the other hand, the focus is on the question of resource allocation and performance justice move. For example, justice is largely incompatible as a concept

with utilitarian considerations, since justice could only be promoted as a contribution to increasing the overall benefit, while from the Aristotelian point of view it is easily addressable.

In the end, t Especially since the clever distribution also encourages us to think continuously about a certain discipline, which has the best effect for the patient, because in the end medical measures should promote the well-being of the patient. In reality, however, the vast majority of medical measures can be seen in a certain risk context. This means that weighing processes are necessary and the principle of do-no-harm can clearly conflict with the principle of beneficence, the principle of justice and even with the principle of autonomy.

Are there any good arguments for the priority – as the "suprema lex" of the doctor – of the nonmaleficence principle "Primum non nocere" over the other principles of autonomy, justice and beneficence? Which at least do not have to be rebalanced every time, but could at least formulate a cautious universal claim? The case is not quite that simple, because in the present situation, the patient's will (ultimately his autonomy) must first be highly respected, not least because a purely classic-paternalistic doctor-patient relationship will survive itself descriptively. It is not without reason that the free choice of doctor is laid down in the relevant professional regulations and thus, in turn, contract autonomy in medical law. § 223 StGB (German Criminal Code) does not apply to medical treatments precisely because "voluntas aegroti suprema lex" (autonomy, informed consent, posthippocratic Cooperation) is seen on the one hand as a priority over "salus aegroti suprema lex" (beneficience, Hippocratic Paternalism), but on the other hand, this contradiction has become fundamentally questionable in today's patient cooperation with the treating doctor. Salus ex voluntate aegroti suprema lex. Education by the doctor and compliance and judgment of the patient are only effective together. These relationships are reflected in legitimate laws (there is also illegitimate legality).

"As a doctor, decide as if you yourself are the patient who does not want to harm themselves or others!" says Steinvorth (1992) pointedly. In a sense, the principle of nonmaleficence (do no harm) is not to be thought of as independent of the other three principles, as was shown here with the example of autonomy; the same applies, of course, to beneficence, which ultimately depends on the benefit, and even justice (suum cuique), because minimising the risk while at the same time maintaining innovation perspectives (which is by no means an obstacle) potentially promotes it, at least it is not fundamentally excluded. Discussing some recent interpretations, Steinvorth comes up with five sensible reasons for nonmaleficence as a wise priority rule of action for doctors:

1. "Before choosing between risky healing and safe damage reduction, the doctor must choose the damage reduction because they do not bear the risk themselves.

2. Compared to the health conditions of his society or of mankind as a whole, the doctor must prevent the prevention of health damage from the promotion of health perfection, because the prevention of damage is a more urgent moral imperative for all people than the promotion of perfection.

3. Orientation to the reduction in damage binds the doctor to the patient's will without delivering them to it. It also places the patient's will on the condition not to harm. It follows the most general and widely recognized principle of action, not to harm, and at the same time corresponds to the idea of human dignity and the inviolability of his will.

4. The "primum non nocere" assigns the doctor a smaller area of activity than the "utilis esse." It therefore reduces the conflicts between the doctor's obligation to the individual and to society. At the same time, it encourages a smaller amount of human conditions to be considered illness than the "utilis esse." But if we can assume with Hermann Lübbe (1988) that "the health status of a cultural community, objectively, rises if, subjectively, it uses the predictor 'sick' restrictively," then we have a specific medical reason for the priority of the "primum non nocere."

5. It is easier to see what harms someone than what is good for them or for their well-being. It is often not easy, but easier. We generally know better, both for ourselves and for others, what we do not want than what we want. The more easily recognisable application of a maxim alone cannot give priority to it, but it must confirm it if there is another reason for it" (Steinvorth 1992).

The justification and application perspectives of the "Primum non nocere" are not trivial, and yet there are some reasons to be aware of at least one high-level principle of action of a medical ethic. In the real dissent situations, especially in the pandemic age, however, this theory has to prove itself repeatedly in the collegial discourse practice of conflicting medical concepts of healing. Indeed, in practice it can be observed that – as Sass puts it succinctly – "[...] the academically educated philosopher [but not only those, SH/PS] [...], who grew up in school contexts, [finds] [...] when weighing up goods [...] that different argumentation patterns are used in different situations, without evident justification conflicts or reasons for having to justify them. We argue categorically and rigorously with Kant on questions of the prohibition of killing. On questions of intervention weighing up criteria of quality of life, we calculate with Mill and others in a utilitarian way. On issues of health care allocation according to the Aristotelian principle of equitable justice (everyone their own!). In accident medicine and in acute crises, the rules of paternalism

and its heteronomous concept of interest apply, in triage situations pragmatic rules and explicit unequal preference for some at the expense of others" (Pöldinger 1991). Of course, the ethics in the corona crisis have once again become essential; however promising it may be, current publications by the German Ethics Council (ethikrat.org/fileadmin/Publikationen/Ad-hoc-Empfehlungen/deutsch/ad-hoc-empfehlung-corona-krise.pdf) or the AEM Academy for Ethics in Medicine e. V. point this out.

Frontline Use Case Bethany Hospital, Moers, Germany – COVID-19-ICU

A current example is the debate on the dissenting of ventilation for acute COVID-19 patients in Germany (the focus here; of course, this debate was and is being conducted internationally).

COVID-19 is a novel disease that was first reported to the WHO in January 2020 as part of the pandemic with the new SARS-CoV-2 virus (Guo et al. 2020). To date, a causal therapy does not exist. Although COVID-19 is asymptomatic to mild in approx. 80 % of cases, approx. 15 % of patients have a severe and approx. 5 % have a critical course with severe pneumonia that can lead to respiratory failure due to a severe oxygenation disorder (Wu and McGoogan 2020). Initial therapeutic recommendations therefore addressed in particular the balancing of hypoxemia with the aim of keeping oxygen saturation above at least 90 % (WHO 2020).

Based on the experience of the first mass attack of patients at the time of the outbreak of the pandemic in China and Italy, recommendations were published – also in Germany by an expert commission – that included a strategy of early intubation and invasive ventilation (Horovitz index of ≤ 200) (Kluge et al. 2020). The entire treatment concept was derived from the principles of ARDS treatment. The treatment results of the critically ill, however, were very poor. In particular, the group of invasively ventilated patients reported from China was extremely bad with a lethality of up to 97 % (Zhou et al. 2020; Wang et al. 2020); the results from Great Britain (lethality 66 %) (icnarc.org/Our-Audit/Audits/Cmp/Reports) and New York (lethality 88 % (Richardson et al. 2020) were also significantly worse than those from invasive ventilation of a septic shock. Even though some of these results come from studies that were published before all included patients had reached the end point of discharge or death and thus improved results from successful treatments appear to be possible, they give reason to critically question the indication and results of invasive ventilation in patients with COVID-19 pneumonia. The high mortality rate of the critically ill also increases the need for targeted therapy.

Drugs were used early on during the pandemic, which are usually used for other viral diseases and which are intended to inhibit the replication of the virus (e. g., the Ebola drug Remdesivir (Wang et al. 2020) or the AIDS drug Ritonavir/Lopinavir (Tobaiqy et al. 2020) or to dampen an excessive response of the human immune system (e. g., drugs from rheumatology such as dexamethasone (Horby et al. 2020) or hydroxychloroquine (Magagnoli et al. 2020. However, the treatment results were sometimes contradictory or even negative (using the example of hydroxychloroquine (Horby et al. 2020), so that – even if praised as a "breakthrough drug" in the media (aerzteblatt.de/nachrichten/113885/Dexamethason-Studie-WHO-sieht-Durchbruch-im-Kampf-gegen-COVID-19) – no general recommendation for the safe use of these drugs could be made. In times of medical uncertainty, however, it makes sense from the risk assessment point of view to rely on reliable knowledge and use analogies. This can and should also include and deliberately reflect the principle of the "Primum non nocere."

At the Bethany Foundation Hospital in Moers (bethanien-moers.de/krankenhaus-bethanien-moers/infos-fuer-patienten1/lungenklinik-lungenzentrum), the principle of "primum non nocere" was the focus from the beginning of the COVID-19 treatments. Here, the ethical reflection clearly supported the medical judgment - despite all the uncertainties and challenges. This treatment concept, which has been referred to in the media as the "Bethany Way" or the "Moerser Model" (rp-online.de/nrw/staedte/moers/corona-moerser-modell-soll-schule-machen_aid-49662005), is based on the one hand on basic pathophysiological considerations, in particular for the treatment of hypoxaemia (Köhler et al. 2005), and on the principle of nonmaleficence by avoiding the use of medication have not been adequately tested in the treatment of the novel disease, which is still largely unknown ex ante, and in the prophylaxis of expected complications such as thrombosis, pulmonary embolism or pneumonia by using appropriate medication. This strategy only provides for invasive ventilation if other measures have not stabilised the patient and intubation seems vitally inevitable. Until then, either oxygen therapy or, if it fails, non-invasive ventilation will be used. The primary goal is to support the patient as long as possible in maintaining his physiological conditions and to maintain spontaneous breathing and vigilance. The effects of positioning techniques such as lying on your stomach or on your side with oxygen therapy and with non-invasive ventilation – similar to invasive ventilation – are systematically checked. It became clear in the brief reconstructive sketch of the technical dissent above that there were deviations from the recommendations made at the outset, since the indication for intubation was not made dependent solely on a limit value for oxygen saturation or the Horovitz index.

The basic pathophysiological relationships speak against this. Accordingly, neither oxygen saturation alone nor the

Horovitz index in pneumonia are suitable for adequately assessing the risk of tissue hypoxia. For this purpose, one should take into account other control parameters such as the oxygen content of the blood or the ejection performance of the heart. The Bethany protocol therefore includes the recording of the basic parameters of oxygen content, cardiac output and respiratory rate. In addition, the patient is continuously monitored for exhaustion by a video camera. In addition to the continuous measurement of the respiratory rate, the ECG is also monitored. To assess the course of the complex inflammatory process, special laboratory parameters such as the CRP and PCT, the LDH, and also the D-dimers are determined daily. The hygiene concept includes a single room, video surveillance, restrictive patient contact through care, thorough ventilation, NaCl inhalations and a non-vented mask with a configuration that prevents the release of infectious aerosols. Neither in this case nor in other cases treated later was there any transfer to the hospital staff. The corresponding results have already been reported elsewhere on a case report. The evidence for the outcome of non-invasive ventilation grows (Karagiannidis et al. 2020). Referring to a current press release of the Bethany Hospital in the context of the visit of Federal Minister of Health Jens Spahn and the Prime Minister of North Rhine-Westphalia Armin Laschet, the mortality of patients under therapy with invasive ventilation would be a dramatic 97 percent in China, 88 percent in New York and still 43 percent in Germany. At Bethany Hospital, the mortality rate for non-invasive therapy would be 1.6 percent. Further data will be published in the near future (bethanien-moers.de/print/krankenhaus-bethanien-moers/ueber-uns/presse/pressemitteilungen/pressearchiv-2020/pe-5720).

The expert recommendation on restrained non-invasive ventilation was given on March 12, 2020 (Kluge et al. 2020), and the WHO guidelines on intubation in the event of failure of oxygen therapy appeared on March 13, 2020 (who.int /docs/default-source/coronaviruse/clinical-management-of-novel-cov.pdf). On March 21, 2020 the "Association of Pneumological Clinics (VPK)" chaired by pulmonologist Thomas Voshaar (working in the same Bethany hospital in Moers (Germany) like the second author of this article) recommended "[...] treatment of respiratory complications from acute viral infection outside the intensive care unit" (vpneumo.de/fileadmin/pdf/VPK_Empfehlung_neu_21.03.2020.pdf), which mainly focused on early and intensive breathing support. On April 7, 2020, Voshaar made a similar statement in the FAZ – "It is too often intubated and invasively ventilated" (faz.net/aktuell/gesellschaft/gesundheit/coronavirus/beatmung-beim-coronavirus-lungenfacharzt-im-gespraech-16714565.html) - which was accompanied by a further intensification of the discussion in specialist circles, but also in a wider public. The possible negative consequences (lung damage, etc.) of ventilation, which may not be indicated at all, were subsequently the subject of much controversy (especially since a shortage of intensive care ventilators from a resource perspective had been discussed, with the corresponding triage fears). On April 9, 2020, a corresponding statement was published, "Ventilation at COVID-19: Pulmonologists Announce Recommendations for Seriously Ill Patients" of the German expert association, "German Society for Pneumology and Respiratory Medicine (DGP)," with a clear rejection of the Bethany position: "The significance of invasive and non-invasive ventilation in acute respiratory failure and COVID-19 is currently being much discussed and commented on. A number of aspects are currently being juxtaposed uncritically, and individual opinions have a weight on the Internet that – from the perspective of scientific societies – they should not get" (lifepr.de/inaktiv/deutsche-gesellschaft-fuer-pneumologie-und-beatmungsmedizin-ev/Beatmung-bei-COVID-19-Lungenaerzte-kuendigen-Empfehlungen-fuer-schwerkranke-Patienten-an/boxid/794408). In the position paper of the DGP dated April 17, 2020 "[...] on the practical implementation of the differential therapy of acute respiratory insufficiency in COVID-19" (Pfeifer 2020), together with Thomas Voshaar, a balancing position is presented, which was essentially incorporated on June 19, 2020 in the S1 guideline "Recommendations for intensive care therapy of patients with COVID-19" (awmf.org/uploads/tx_szleitlinien/113-001l_S1_Intensivmedizinische-Therapie-von-Patienten-mit-COVID-19_2020-06_1.pdf). There, clause 10 states: "The implementation of intensive care treatment for patients with COVID-19 follows the essential ethical principles such as autonomy, beneficence, nonmaleficence, justice and human dignity. An admissible treatment measure must meet two requirements: 1. for the beginning or continuation, according to the treating physicians, there is a medical indication, and 2. the implementation corresponds to the patient's will. If the treatment measure tested meets both requirements, treatment must be initiated or continued. If one of the two conditions are not met, a change in the therapy goal and limitation of the therapy is not only allowed, but even required."

"Primum non nocere" Against All Pandemic-Odds

Medicine is not an easy business. As a patient you ask yourself: "Should I emphatically demand ventilation as a COVID-19 patient, or should I trust doctor A's indication, when doctor B says otherwise and the experts obviously do not agree anyway?" This question arises not only existentially, but already in the case of small sensitivities that motivate some patients to have a very different culture

of dialog with their own doctors. Both ethical and medical reasons are addressed here, doctor and patient. Doctors are not gods, not even half-gods, but as good doctors they are prepared for the daily, often hard, examination of ethical values in dilemma situations (for which very good training is essential) and they can and should cooperate with the patients and vice versa. Asymmetry does not become symmetry – but not least in the digital age, it is another form of discourse. And at the end of the treatment. Innovation and nonmaleficience/beneficence fosters when it comes down to research a special patient-relation, because e.g. "without patients volunteering to participate in clinical research for fear of the possibility of harm, the potential benefits would never be realised and the progress of medicine would come to a halt" (Schwartz 2004). Patients are in turn dependent on a broader base of solid knowledge (beyond fake news) in order to choose the indeed healthy middle of the argument beyond panic and serenity in the spirit of Aristotelian understanding of virtue. "Medicine rests on a broad theoretical basis. But it is not an exact natural science; although it uses scientific methods, it is also philosophy, and above all it is practical action under ethical maxims" (Koslowski 1992). This has to be remembered again and again. The technical debates are not only to be endured individually, but as the core of the medical ability to be innovative without taking inappropriate risks, to be recognised for ethical reasons. It is important, of course, that it is about the issue and its positive effects (healing and damage prevention) for the patient – not systemic attributions in a hierarchical ordologic of institutionalised medicine that is still top hierarchical. Especially in the current pandemic crisis of an unprecedented socio-economic global extent (and probably also medically very demanding), the position of ethics is being brought to the centre. Obviously, doctors do not have to have the same professional view, and ethical judgments can differ as well. The sensible, open and collegial discourse of the medical profession and related disciplines (such as ethics, computer science, sociology ...) is perhaps the best thing that is available for the patient in order to achieve human, effective and low-risk healthcare. In the future, medicine in its application form as medical and nursing activities (and more forms we cannot even imagine today) will continue to work according to rules that are often controversial, but can and should ultimately lead to good outcomes for the patient. As seen, dissent often arises less on the normative than on the descriptive level. The question as to which form of treatment is the one that leads to the maximum possible success for the lowest risk costs for the patient is often disputed. Also, because medical research needs time to be good. And data to be substantial. Perhaps one perspective of digital medicine of the future is to be able to resolve descriptive dissent more quickly with more and, above all, better data without involving patients in factual treatments in the research. But even these possibilities offered by digital technologies will not be able to relieve the responsible actors in the health care system from the exhausting business of operating ethics. Weighing up values under considerable time pressure, existential fates and critically discussed evidence is a considerable challenge for every responsible person, a real superpower. Not only in pandemic times.

Acknowledgement

The authors would like to thank R. Kinsella for assistance with the translation of this text from German to English.

Conflict of Interest

None. ■

Key Points

- Ethics is the Superpower in Medicine
- Do-no-Harm in the Context of the "The Big Four" "middle principles" in medical ethics
- Frontline Use Case Bethany Hospital, Moers, Germany – COVID-19-ICU: "Primum non nocere" against all Pandemic-Odds

References

Beauchamp TL, Childress JF (2001) Principles of Biomedical Ethics, Oxford (Original 1977)

Bergdolt K (2004) Das Gewissen der Medizin - Ärztliche Moral von der Antike bis heute, München

Brenner A (2006) Bioethik und Biophänomen - Den Leib zur Sprache bringen, Würzburg

Crockett LJ (2019): AI Ethics - The Thin Line between Computer Simulation and Deception, in: Griffiths P, Kabir M N (Eds.): ECIAIR 2019 European Conference on the Impact of Artificial Intelligence and Robotics, Oxford, 80-87

von Engelhardt D (2005) Medizinethik im Wandel der Zeit. Monatsschr Kinderheilkd 153, 42–47 (2005) - https://doi.org/10.1007/s00112-004-1066-1

Engelhardt HT Jr (1996) The Foundation of Bioethics, New York

Gethmann-Siefert A, Thiele F (Eds.) (2006) Ökonomie und Medienethik, München

For full references, please email editorial@icu-management.org or visit https://iii.hm/14w0