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Abstract

There's evidence that implementing the four medical ethics principles may be challenging especially in low income country contexts with extreme resource scarcity and limited capacity to facilitate deliberations on the different ethical dilemmas. These challenges can partly be explained by the social, economic, and political contexts in which the decisions are made, as well as the limited time, training and guidance to facilitate ethical decision making. Based on current literature, and using the example of bedside rationing; this chapter synthesizes the challenges clinicians face when operationalizing the four principle; identifying the opportunities to address them. We suggest that clinicians' ability to implement the four principles are constrained by meso- and macro-level decision making as well as their lack of training, explicit guidelines, and peer support. To ameliorate this situation, current efforts to strengthen the clinicians' capacity to make ethical decisions should be complimented with developing of context relevant guidelines for ethical clinical decision making. The renewed global commitment to the sustainable development goals and universal healthcare coverage should be recognized as an opportunity to leverage resources and champion the integration of equity and justice as a core value in resource allocation at the bedside, meso-, macro- and global levels.

Keywords: principles of medical ethics, bedside rationing, low-income countries

1. Introduction

There is general acceptance of the four medical ethics principles of autonomy, beneficence, non-maleficence, and justice. These principles were developed in 1978 by the United States national commission for the protection of human subjects of health research involving human beings.

Originally, the commission identified three principles with corresponding (areas of application), namely respect for humans (informed consent); beneficence (assessment of risks and benefits); and justice (selection of human subjects) [1]. Since then, these principles form the basis of training in ethics for practitioners worldwide [2]. While these principles provide valuable guidance for practitioners, their applicability could be enhanced if they are contextualized, especially in the cases of low-income countries (LICs) where resources are extremely scarce [3]. Questions that may arise include the following: How do you obtain informed consent from a patient who is desperately in need of care and being unable to understand the treatment options—defers the decisions to the practitioner? How does a practitioner ensure that their “intervention” is of benefit to the patient when they do not have the resources to provide the best intervention? Furthermore, how do they ensure justice in the allocation of resources in the context of extreme resource constraints?

In contexts where resources are limited, rationing is recommended although it is contentious. There is a growing body of literature on bedside rationing (defined as the withholding of potentially beneficial treatment or medical procedure from a patient) [4–8]. While the literature highlights the general rationing challenges mainly related to the physicians’ dual role as patients’ advocates and society’s gate keepers, this literature also clearly shows that in addition to the general challenges, health practitioners in low-income countries are faced with many unique ethical challenges in their practice, with dire consequences for both themselves and their patients [7–9]. This could partly be explained by (i) the context in which they practice which is characterized with low literacy rates, poor infrastructure, poverty, marked social, health inequalities; limited government commitment to equitable health systems and the global health context; (ii) their training in medical ethics and the availability of explicit guidelines for decision making; and (iii) external pressures.

This chapter highlights the challenges practitioners working in low-income countries (LICs) face when operationalizing the general principles of medical ethics. We expound on the principle of justice, using the example of bedside rationing, and discuss how these decisions are made and their ethical implications and challenges. In next sections, we will first provide an overview of the LIC contexts, identifying the factors that could influence ethical decision making; second, we will discuss the challenges related to operationalizing the four principles; and third, we will use the case of bedside rationing to expound on the justice principle and the related challenges. In the last section, we will discuss the current opportunities and potential interventions that would alleviate the challenges faced by practitioners in low-income countries.

2. The context of medical ethics and bedside rationing in low-income countries

According to the World Health Organization, low-income countries share similar characteristics of high levels of population poverty, poor physical infrastructure, lower literacy levels, and weak health systems as illustrated in the **Table 1**.

Indicator	Value
Gross domestic product	\$397.8
Population living on less than \$1.90/day	47.2%
Literacy level	57%
Rural population	70%
Health expenditure per capita	\$37
Hospital beds/1000 population	0.8
Physician/1000 population	0.1
Births attended by trained staff	50%
Life expectancy at birth	61 years
Infant mortality rate/1000 live births	53

Source: <http://data.worldbank.org/income-level/LIC> (Accessed June, 2016).

Table 1. Socioeconomic characteristics of low-income countries.

As demonstrated in **Table 1**, the limited resources available to the health system in most low-income countries (\$37 per capita compared to the >\$1000 for most of the OECD countries) have resulted in ad hoc availability of medical supplies and limited and often poorly motivated health workers. The dismal human resources/population ratios means that poorly motivated health workers have a very high patient load [10], which impacts the amount of time a clinician can spend with a patient and their quality of care. This situation is worse for the poor, rural populations where due to a lack of physical infrastructure and poor access to opportunities, health workers are often reluctant to live and work in these areas [10].

Most LIC governments, recognizing these problems, have embarked on re-structuring their health systems in order to improve population access to quality healthcare services. This has been achieved through the commitment to universal health coverage and the re-orientation of services to primary health care and building and strengthening the primary care network. There have also been attempts to strengthen the referral system to ensure that only referred patients are sent to hospitals [11]. However, in many cases, the referral system has not functioned as planned, due to the limited and often ad hoc availability of medical supplies at the lower levels. Patients end up crowding secondary and tertiary level units where they are likely to be seen by a specialist and are more likely to receive treatment [12].

The resource constraints experienced by health systems in LICs are a reflection of these countries' low GDP and their limited per capita health expenditure. Some scholars have strongly argued that since governments are unable to meet their commitment to publicly finance the health systems, alternative financing mechanisms should be sought [13]. However, while health insurance has worked in places where most of the population is formally employed, it has not worked well in most LICs where 70% of the population is rural and employed in the informal sector. Organizing and managing such a system has proved to be more costly than its benefits. There have also been attempts to introduce user fees; however,

in several contexts, this has also failed due to the financial barrier it introduces, for especially the poor. Hence, in the interest of equitable access, this has been abandoned [14].

Within this context, medical education emphasizes and urges providers to uphold the standard four principles of medical ethics. However, the context of extreme poverty, low literacy levels, social-economic and health inequities, poor infrastructure, and weak health systems may present challenges for clinicians who may wish to operationalize these principles. We explore these in detail in the next section.

3. The principles of medical ethics and their operationalization in low-income countries

Medical ethics hinge on four principles, namely autonomy, non-maleficence, beneficence, and justice. We discuss the challenges related to operationalization these principles in LICs.

3.1. Autonomy

According to this principle, patients should have the freedom in thought, intention, and action to make informed choices with regard to their treatment. They should be provided with adequate information on the risks and benefits of an intervention and should not be influenced or coerced into making a particular choice. Individuals should also be able to understand the consequences of his/her actions [15]. Inherent to this principle is the assumption that the patient has the capacity, understands, and is capable of acting independently without outside influence and that they want to engage in the process of determining their treatment. A secondary assumption is that the patient wants to independently make these decisions.

While these assumptions might hold in some contexts, several contextual factors limit the ability of LIC clinicians to uphold this principle. The high clinician:patient ratio and low literacy levels may make it difficult for clinicians to adequately explain treatment options to patients and may make it difficult for patients to adequately understand the information that is provided in order for them to make independent, informed choices. Moreover, in some cultures in Africa, it is unacceptable for sick people to be “burdened” with making decisions about their health, neither do they believe in individualized decision making [2]. In other instances where gender inequities are prevalent, women are often prohibited from making decisions independent of their husbands. As such, patients’ ability to choose family and cultural interests and the physician’s obligations in relationship to autonomy can, at times, be in conflict, leaving physicians with the challenge of how to handle these different interests while still upholding the ethical principles [16].

While the discussion of autonomy often exclusively focuses on the patient, here we, of necessity also reflect on clinicians’ autonomy in medical decision making. While it is often assumed that clinicians have the autonomy to make independent decisions in their patients’ best interests, this assumption is flawed within the LIC context. First, most LICs provide an essential drug list which might limit clinicians’ autonomy in deciding the drugs they can

prescribe for their patients [17]. Second, a lack of infrastructure and other medical technologies constrain clinicians' autonomy to decide when and how to treat their patients. Finally, due to low salaries, clinicians may be liable to coercion by pharmaceutical companies to use the drugs and technologies they want to promote. On the other hand, due to the lack of regular supply of drugs and poverty among patients, some clinicians, in the quest to do what is best for their patients in the face of scarcity, may be forced to use the samples of drugs introduced by the pharmaceutical companies, since the samples are free. While this may seem reasonable at the time, in that the patient gets some treatment at the time; it raises questions with regard to whether or not the patient is able to obtain the full course of the drug (which can be costly especially if newly introduced), and if they are unable to, then the benefits are short lived [18, 19].

3.2. Non-maleficence

According to this principle, a clinician should not intentionally cause harm to a patient or society either by commission or by omission. They should also do whatever is possible to prevent any harm to the patient [20]. Clinicians should have the competency to provide the appropriate standard of care and the authority and freedom to make clinical decisions [1].

Medical schools in LICs endeavor to provide the best possible education to their trainees, equip them with the knowledge and competencies they need to practice medicine, and provide the appropriate standard of care [21]. However, an extreme lack of resources, especially drugs and medical supplies, often forces clinicians to make decisions (with regard to the choice of treatment or medical procedure), which may not adhere to the standard of care and could potentially be harmful to patients and society. For example, in some cases, clinicians are unable to ensure that the patients get the full course of the necessary antibiotics, which puts patients at risk of developing drug resistance, which is detrimental to both patients and society [22]. The dilemma faced by these clinicians then is whether to defend a patient's or society's interest. Withholding limited drugs from patients who are unlikely to be able to afford to complete the prescribed treatment would prevent these patients from developing drug resistance, which is good for both the patient and society. However, the patient may not perceive it as beneficial in that moment. The other option would be to honor the patient's request and provide whatever drugs that are available, although inadequate, to the patient, even if the practitioner knows that the patient would not afford to pay for the rest of the treatment. While this would appease the patient, it may be detrimental to both the patient and society in the long run, when such patients develop drug resistance. Unfortunately, some clinicians, due to the various reasons discussed above, are more likely to take the second option [7].

3.3. Beneficence

This principle, sometimes perceived to be the opposite of maleficence, is based on minimizing risks and maximizing benefits. At the bedside, it relates to the clinician's commitment to doing what is right, an act of charity, mercy, or kindness to another person. In this context, it is the moral obligation for clinicians to ensure that any procedures or treatment given to the patient is intended to benefit the patient and minimize risk [23]. This requires clinicians to have the

appropriate skills and knowledge, the ability to understand and assess the individual patient's circumstances and to assess the risks and benefits of the available treatment options, in order for them to confidently determine that the treatment option would definitely benefit the patient and cause them no harm [23, 24].

Similar to the previous principles, beneficence assumes that the clinicians are in complete control of making and executing any clinical decisions that they deem beneficial to their patients. However, while they may have the expertise, intention, and commitment to act morally, out of charity, mercy, and kindness towards their patients to ensure that their patients benefit, a general lack of resources, and the inability of the patients to access the treatment of choice means that clinicians' commitment to benefit the patient is not always possible [7, 8].

Another challenge relates to the ability of the clinicians to confidently determine that the available treatment would benefit (and not harm) the patients. This necessitates ensuring that the benefits of any procedure or treatment outweigh the risks. However, most of LIC clinicians are not always able to assess this; it may not even be possible to accomplish this at the national level. Such situations result from a lack of the capacity at the national or hospital laboratories to test procedures as they are developed in order to assess their applicability within the local context.

Some of these challenges could be explained by reflecting on the global research and development for new drugs. Due to low research capacity in most LICs, many of the drugs are developed and tested in high- or middle-income countries [25]. The context of the drug development differs from the LIC context where most patients are likely to have comorbidities and may respond to the treatment differently [26]. While having well-functioning laboratories and research capacity within LICs would help clinicians to assess the effectiveness of these drugs within this context; in many cases, national laboratories are ill-equipped and lack the capacity to conduct these complex assessments. Moreover, the rate at which new drugs and technologies are developed does not give clinicians adequate time to review and evaluate information related to one new drug before another drug or technology is introduced and promoted [27]. For these reasons, clinicians are forced to make decisions with regard to adopting new drugs without complete knowledge of how the patients may react to the treatment and are therefore unable to say definitely that they are fulfilling the beneficence principle.

3.4. Justice

This principle relates to fairness in the allocation of health resources including drugs, practitioner's time, and health facility procedures. Sometimes this is interpreted in terms of distributing resources: either equally in society/or to individuals; or according to need, share, effort, contribution, merit, and free-market exchanges [28]. While the distribution of health resources occurs at the different levels of decision making, this paper focuses primarily on the distribution of resources at the bedside. We expand on the challenges related to this principle in relationship to clinical decision making at the bedside in LICs. The discussion in this section also draws on the prior discussion of the three principles of medical ethics.

4. The challenges related to the principle of justice: a look at allocating resources at the bedside in LICs

In order for us to understand the challenges related to bedside rationing in low-income countries, we will start by reviewing some of the literature on the rationing of treatment in low-income countries, then present cases of the rationing process of drugs from the literature, discussing the challenges. Finally, we propose some ways to address these challenges.

There is meager literature on bedside rationing in LICs. Kafiriri and Martin, 2007 [8] describe bedside rationing in a hospital in Uganda. This study provides a detailed decision making process that clinicians follow when making medical decisions—which were often related to setting limits to treatment access. Decisions about who receives first-line treatment, which patient is seen first and who gets to go the operating room were discussed. This study reported that clinicians considered both acceptable and non-acceptable criteria when making these decisions. The decisions were constrained by decisions made at the national and global levels. In another study, Defaye et al. [9] conducted a national survey of clinicians, the majority whom reported to frequently make rationing decisions in relationship to referrals for surgery, ICU, and prescription drugs. Many had witnessed the adverse effects of bedside rationing including death and disabilities. Both these cases documented physicians experiencing moral distress as a result of making the rationing decisions.

This literature demonstrated that while the clinicians had the capacity to make definite diagnoses and prescribe the first-line treatment for the patients, the availability of the prescribed treatment or procedure forces clinicians to consider if the patients are able to purchase the first-line treatment, if not, they receive the second-line treatment. While these decisions are sometimes made with the patients, sometimes, they are independently made and not guided by an explicit criteria or guidelines [7, 8, 18]. These findings are similar to those of a study conducted in India on rationing of care for neonates [29].

The challenges that clinicians face seem to be consistent across countries. We summarize the above challenges in **Table 2**.

Some challenges were common to all the three cases: the context of extreme resource scarcity, lack/inadequacy of explicit guidelines, the challenge of having to forego the first-line treatment due to scarcity of resources, and the challenge to choose what patients to withhold treatment from. There were practitioner-related challenges which were also common to the three contexts: the use of unacceptable criteria, the dual role of practitioners, witnessing the consequences of the rationing decisions, and the resulting moral distress. Lack of education resulting in inability to discuss the decisions with patients and the patients' differing the decisions to the clinicians were common to the three cases.

Only three challenges were identified in only one context. Disagreements among health professionals with regard to how to ration care in the Ethiopia study, lack of forum for discussing ethical issues in the India case study, and the lack of credible in the Uganda case study. The rest of the challenges were common to at least two of the case studies.

While structural factors: poverty, lack of education, lack of medical supplies present insurmountable challenges, some of the challenges such as lack of guidelines for decision making, lack of proper training in making fair rationing decision are modifiable and present opportunities for improvement [7, 8, 18, 29].

Types of challenges	Ethiopia	India	Uganda
<i>Contextual challenges</i>			
Resource scarcity	X	X	X
Patients' socioeconomic status: poverty, education	X	X	X
<i>Decision making process-related challenges</i>			
Lack of training in resource allocation ethics	X		X
Lack/inadequacy of guidelines	X	X	X
Disagreements among professionals	X		
Foregoing first choice treatment	X	X	X
Choice of patients to restrict access to treatment	X	X	X
Balancing patient and family interests	X	X	
Lack of credible evidence			X
No forum for discussion ethical issues		X	
<i>Practitioner-related challenges</i>			
Perceived lack of control of the decision yet held responsible		X	X
Feelings of helplessness and incompetence		X	X
Use of unacceptable criteria and how to deal with it	X	X	X
Dual role of the physicians	X	X	X
Witnessing and feeling responsible for the consequences of rationing for the patient	X	X	X
Moral distress	X	X	X
<i>Patient-related challenges</i>			
Inability to communicate due to lack of knowledge	X	X	X
Differing decisions to doctors		X	X
Excessive demand by "able" patients		X	X

Table 2. Sample of documented bedside rationing challenges in low-income countries.

5. Discussion

Several interventions are proposed to deal with the above challenges and facilitate the implementation of the four principles of medical ethics in LICs. We discuss these in detail.

5.1. Opportunities and interventions at the bedside

- i. *Contextualize the principles of medical ethics:* While bioethics principles are accepted globally and used as basis for medical training, the realities in LICs make it impossible

for clinicians to implement these principles as postulated. As discussed above, the social, economic, and cultural contexts where the medical decisions are made constrain the application of these principles. Given the critical relevance of ensuring that clinical practice is ethical even in LICs demands that medical ethics remain at the core of medical training. However, the above challenges would require that the principles are contextualized [2]. This would entail not diluting them, but ensuring that they are relevant and can provide meaningful guidance to the clinicians who should apply them. This could be achieved by introducing the ideal principle but supplementing these with relevant case scenarios from the local context, in order to ensure that trainees engage and understand how these principles can be applied within their context and the related dilemmas. This would enable students to think through the different challenges they might face and develop context-sensitive strategies.

- ii. *Develop explicit medical ethics and rationing guidelines:* The literature to date highlights that practitioners in LICs lack explicit guidelines for use when making limit setting decisions. This does not seem to be an integral part of their training in bioethics. There is hence, need for LIC medical schools, in conjunction with ethicists to develop explicit guidelines for clinicians. This would not only ensure consistence in their decision making but would also contribute to reducing the clinicians' moral distress if they know that their decisions would be supported by other clinicians. Such guidelines should include clear decision making flow diagrams, with explicit criteria (both medical and otherwise) which should be developed with input from the public [7, 8, 18]. The guidelines should also include the principles of procedural justice in resource allocation. This entails ensuring that the criteria used is relevant to the decisions, that the decisions and criteria are publicized, that there are provisions for appealing and revising the decision and that there are voluntary mechanisms to ensure adherence to this process [28]. These guidelines would be an integral addition to the existing medical ethics courses in the schools of medicine.
- iii. *Strengthen in service peer support systems:* In addition to training and developing decision making guidelines, there is need for regular clinical discussions on the ethical challenges faced by practitioners [29]. This could be part of the routine clinical departmental meetings that are regularly convened to review patient care. Facilitating dialogue about the ethical challenges and how to best handle them would serve to mitigate the moral distress that clinicians experience. Furthermore, such a forum could also be used to re-emphasize the consistent use of the guidelines and their revision where necessary.

5.2. Opportunities and interventions at the health institution level

- i. *Support the efforts at the micro-level:* Since the clinicians work under the leadership of health institutions, it is critical for micro-level interventions to be supported by the institution leadership. For example, the guidelines developed to guide clinicians in

ethical decision making with regard to resource allocation could be formalized for use across the clinical departments.

- ii. *Lead by example:* The institutional administrators should lead by example by implementing fair priority setting processes at their level of decision making [28]. In order to facilitate this, the institutions should develop explicit priority setting processes, with criteria which is developed in conjunction with clinicians. These criteria should be published with the institution and debated, it should also reflect the relevant criteria identified at the micro-level. Once resource allocation decisions are made, they could be disseminated through an institutional newsletter, where available and also posted on the institutional webpages. The management of the institution should also establish clear mechanisms for appealing the decisions. While many institutions have used suggestion boxes, these have been found to be ineffective [18]. A designated office that handles complaints related to the allocation of resources may be more accessible to the public. Information about this office should be publicized. This internal office could also be responsible for ensuring that the conditions for fair priority setting are met within the institution.
- iii. *Capacity building:* There is consistent observation that decisions made at the meso-level and macro-level constrain the bedside rationing decisions [18, 29]. If the hospitals do not facilitate shared decision making and transparency in their decision making, it is unlikely that the clinicians will abide with the proposed limit setting decisions. Furthermore, availability of resources at this level determines the resources that clinicians have for use. In many cases, hospital managers are not clinicians and may not necessarily be trained in medical ethics or in medical resource allocation principles [7, 8, 29]. In cases where officers have not received this critical training, there should be in-service training of all institutional leaders in the principles of justice in the allocation of resources. An example of such training has been introduced in Ethiopia where clinicians and leaders in health are trained in medical ethics, including justice in resource allocation [30]. This could be a model that could be duplicated in other LICs in order to strengthen the capacity of hospital managers and clinicians to make ethical resource allocation decisions.

5.3. Opportunities and interventions at the national level

- i. *Political will and commitment:* While it is important that clinicians and hospital managers receive training and facilitate fair resource allocation decision making, these would not address the LIC contextual factors that constrain their decision making. Concurrent efforts at the national level need to focus on:
 - a. *Increasing the health sector budget:* While it is understood that LICs have limited resources, countries need to commit to at least meet the Abuja declaration on government funding of the health sector [31]. While LICs have, in the past, depended on donors to support their health sectors, this ought not to be the norm since it is non-sustainable and has the repercussions of having national priorities

influenced by non-state stakeholders. Priority setting, if done well, would help governments focus on what is feasible and sustainable within their budgets.

- b. Strengthening health system and infrastructure and allocating adequate resources to at the very minimum deliver the essential health services. While most LICs have defined a basic healthcare package, not many have been able to deliver all the basic services. Sited limitations include a mismatch between the package and both financial and human resources available to deliver it [32]. The limited resources often mean that clinicians do not have the basic drugs and diagnostics to treat the patients effectively. It is hence unlikely that the challenges faced by clinicians can be successfully mitigated without addressing these contextual factors. The recent committed to achieving Universal Health Care coverage by most of the low-income countries provides a unique opportunity for strengthening health systems; however, this needs to include concurrent efforts to ensure that the package serves those who are most in need of the services; the use ethical principles to allocate the available resources, with specific attention to equity in access is critical [33].
 - c. Improving decision making at the national level: National level priority setting in many LIC health system has been described as ad hoc due to lack of explicit processes and the resources to implement the identified priorities. This results in a high potential for national priorities to be overlooked during implementation [34]. While there are national level processes where priorities are identified, they are often aligned with the essential service package (discussed above), which governments are unable to fund. Governments should use the universal health access commitment to identify realistic services (within the available resources) services that their populations, especially the most vulnerable should have access. Similar to the meso-level, the existing decision making processes need to be strengthened by the following: establishing explicit fair priority setting process which is participatory, transparent and accountable. The public should inform and be informed about this process with the publicity of both the decisions and criteria [27, 33]. Governments also need to devote resources to addressing the key non-health system determinants of health that impact the population access to health and health care such as education and poverty [35].
- ii. *Facilitate public awareness and education:* The public is often unaware of the need to ration care. This is worsened by the politicians' reluctance to discuss the realities of lack of medical supplies and human resources in the health institutions with the general population [36]. In order to empower patients (and the public), health ministry's should facilitate open discussions about the limited resources and the need to ration, at the different levels. Public values and preferences with regard to priority setting should be elicited and be used as input to priority setting processes. While this might be constrained by the low population literacy levels, presenters of such information should use innovative strategies, for example, using the balanced sheet, charts, and diagrams, to ensure that the information is accessible to the public [37,

38]. The existing decentralized political and governing structures provide an opportunity for public engagement since one of the purposes of decentralization is to take decision making closer to the people and facilitating public engagement in decision making.

5.4. Opportunities and interventions at the global level

The renewed global commitment to the Sustainable Development Goals, with health and well-being as goal 3, presents an opportunity for leveraging resources for LIC health systems since most of the health systems within low-income countries are supported development assistance partners [39]. This interest and commitment by development partners to invest in health interest should be meaningfully exploited. Some of these resources could be committed to strengthening and supporting the priority setting and ethics infrastructure within LICs.

Global level stakeholders also need to observe the key guiding principles of fair decision making when deciding where to invest their resources. These processes should consider information and priorities within the countries they may wish to support. Furthermore, global partnerships should aim at realizing equitable access to drugs by ensuring that their research and development investments are made fairly reflecting equity. Once the drugs and diagnostics are developed, there should be frameworks to ensure that LICs can access the new innovations. The challenge for the WHO is to strengthen such existing frameworks [40]. However, the ethical principles especially conflict of interest should be carefully monitored in such partnerships.

6. Conclusions

The context of decision making in low-income countries constrain clinicians' ability to implement the principles of medical ethics and especially justice when caring for their patients. Efforts that have focused entirely on strengthening the capacity of clinicians in medical ethics, without addressing the contextual factors that constrain these decisions are limited. There is need for concurrent efforts to focus at the meso-, macro- and global levels so as to ensure that the context where practitioners make medical decisions is conducive for ethical decision making.

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