UNIT NO. 6

MEDICAL ETHICS IN THE CONTEXT OF VACCINATIONS

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ABSTRACT

The objectives of this review are to provide an update on medical ethics in the context of vaccinations.

Vaccinations are effective solutions of controlling vaccine preventable infections. However, like any medication, they have the potential of causing minor adverse effects. Also, such adverse effects may be blown out of proportion if the myths and misconceptions remain unchallenged with evidenced information. The result will be a growing distrust to anyone advocating vaccination. The new ethical strategy is to deal with vaccine rejecter and vaccine hesitant respectfully. It is ethically incorrect to view vaccine sceptics as ill-informed or less educated individuals. By maximizing the opportunities for engagement and discussion of patient or parental vaccine concerns, the potential for a change in decision making towards vaccine acceptance is big. In acute humanitarian emergencies - the 3 Rs – rationing, restrictions, and responsibilities – provide a framework for rapid correct ethical decision making.

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INTRODUCTION

1-The boon of vaccinations

Dr Edward Jenner's discovery of vaccination against small pox using cow pox in the eighteenth century and his attempt to send his observations to the Royal Society in 1801 of marked the beginning of one of key medical advances in medical science.[1]

Small pox was a devastating disease. On average, 3 out of every 10 people who got it died. Those who survived were usually left with scars, which were sometimes severe. Blindness occurred from small pox pustules appearing on the cornea and healing with scarring. Small pox is thought to date back to the Egyptian Empire around the third century BC. The mummy of Rameses V had pustules on his head to indicate he died of small pox. In May 1980, the 33rd World Health Assembly declared the world free of this disease[2].

2-Mandatory vaccinations and ethical struggles of today

As a consequence of the vaccine discoveries of the twentieth century, parents and many healthcare providers of the twenty-first century have limited or no experience of the devastating effects of small pox, polio, or measles. The dread of these diseases is replaced by struggles and debates of vaccine safety and vaccination refusals[3]. The world is reminded of the consequences of such refusals by disease outbreaks and vaccine preventable deaths from diseases already conquered. The resurgence of measles in United States in 2014-2015 (Disneyland Measles) is a recent example in point[4].

3-Ethically acceptable and unacceptable exemptions

Exemptions from vaccinations are ethically acceptable if they are based on medical grounds. Is there a moral right to nonmedical vaccine exemption? [5].

4-Objectives of this review

The objectives of this review are to provide an update on medical ethics in the context of vaccinations. The following areas are covered:

- Framework of medical ethics and vaccinations
- Is there a moral right to nonmedical vaccine exemption?
- Vaccine hesitancy and trust
- Parental vaccine refusal
- Vaccination ethics in public health emergencies: rationing, restriction, and responsibilitites.

FRAMEWORK OF MEDICAL ETHICS AND VACCINATIONS

1-Medical ethics principles

The medical ethics practice of today consists of 4 key principles and the medical context. These are:

- Respect for autonomy – Capable patients must be allowed to accept or refuse recommended medical interventions
- Beneficence – Medical practitioners should act in the best interests of the patient
- Non-maleficence – Medical practitioners must not harm the patient
- Distributive justice – Health care resources should be distributed in a fair way among the members of society[6].

In public ethics, two other medical ethics concepts are added: Act utlilitarianism and Rule utlilitarianism - See page 21.

2-Vaccines and vaccinations

Vaccines can be divided into two broad groups: live attenuated vaccines and killed/inactivated vaccine. The first human vaccines against viruses used weakened or attenuated viruses to generate immunity. The smallpox vaccine used cowpox, a poxvirus that was similar enough to smallpox to protect against it but usually didn't cause serious illness. Rabies was the first virus attenuated in a lab to create a vaccine for human beings[7]; out of this attenuated virus a killed/inactivated vaccine is created. The rabies vaccine will not cause rabies[8].

Vaccines in use today are made using several different processes. They may contain live viruses that have been attenuated (weakened or altered so as not to cause illness); inactivated or killed organisms or viruses; inactivated toxins (for bacterial diseases where toxins generated by the bacteria, and not the bacteria themselves, cause illness); or merely segments of the pathogen (this includes both subunit and conjugate vaccines) [7]. See Figure 1.

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Figure 1. Vaccine types and diseases they prevent	
Vaccine type	**Childhood immunization vaccines**
Live, attenuated	Measles, mumps, rubella (MMR combined vaccine) Varicella (chickenpox) Influenza (nasal spray) Rotavirus
Inactivated/Killed	Polio (IPV) Hepatitis A
Toxoid (inactivated toxin)	Diphtheria, tetanus (part of DTaP combined immunization)
Subunit/conjugate	Hepatitis B Influenza (injection) *Haemophilus influenza* type b (Hib) Pertussis (part of DTaP combined immunization) Pneumococcal Meningococcal
Vaccine type	**Other available vaccines**
Live, attenuated	Zoster (shingles) Yellow fever
Inactivated/Killed	Rabies
Subunit/conjugate	Human papillomavirus (HPV)
Source: College of Physicians of Philadelphia, 2018,[7] adapted	

Live, Attenuated Vaccines

The most common methods used in creating attenuated vaccines involve passing the disease-causing virus through a series of cell cultures or animal embryos (typically chick embryos). With each passage, the virus becomes better at replicating in chick cells, but loses its ability to replicate in human cells. A virus targeted for use in a vaccine may be grown through—"passaged" through—upwards of 200 different embryos or cell cultures[7].

When the resulting vaccine virus is given to a human, it will be unable to replicate enough to cause illness, but will still provoke an immune response that can protect against future infection. One concern is the potential for the vaccine virus to revert to a form capable of causing disease. This is very unlikely, as the vaccine virus's ability to replicate at all is limited; however, it is taken into consideration when developing an attenuated vaccine. It is also worth noting that mutations are somewhat common with the oral polio vaccine (OPV), a live vaccine that is ingested instead of injected. The vaccine virus can mutate into a virulent form and result in rare cases of paralytic polio. For this reason, OPV is no longer used in the United States, and has been replaced on the Recommended Childhood Immunization Schedule by the inactivated polio vaccine (IPV).

Killed or Inactivated Vaccines

One alternative to attenuated vaccines is a killed or inactivated vaccine. Vaccines of this type are created by inactivating a pathogen, typically using heat or chemicals such as formaldehyde or formalin. This destroys the pathogen's ability to replicate, but keeps it "intact" so that the immune system can still recognize it. ("Inactivated" is generally used rather than "killed" to refer to viral vaccines of this type, as viruses are generally not considered to be alive.)

Since killed or inactivated pathogens cannot replicate at all, there is no risk that they can revert to a more virulent form capable of causing disease. The downside is such vaccines tend to have a shorter length of protection compared to live vaccines, and are more likely to require boosters to create long-term immunity.

Killed or inactivated vaccines on the U.S. Recommended Childhood Immunization Schedule include the inactivated polio vaccine (IPV) and the seasonal influenza vaccine (in shot form) See Figure 1. Figure 2 shows the Singapore National Childhood Immunization Schedule. Note that IPV is given in the first 4 immunisations but the 5th one given at 10-11 years is an OPV to give a more lasting immunity.

Figure 2. National Childhood Immunisation Schedule, Singapore 2016

Vaccination against	Birth	1 month	3 months	4 months	5 months	6 months	12 months	15 months	18 months	10-11 years^
Tuberculosis	BCG									
Hepatitis B	HepB (D1)	HepB (D2)			DTaP (D3)#					
Diphtheria, tetanus and pertussis			DTaP (D1)	DTaP (D2)	DTaP (D3)				DTaP (B1)	Tdap (B2)
Poliovirus			IPV (D1)	IPV (D2)	IPV (D3)				IPV (B1)	OPV (B2)
Haemophilus influenzae type b			Hib (D1)	Hib (D2)	Hib (D3)				Hib (B1)	
Measles, mumps and rubella							MMR (D1)	MMR (D2)##		
Pneumococcal disease			PCV (D1)		PCV (D2)		PCV (B1)			
Human papillomavirus	*HPV2 and HPV4 are recommended for **females aged 9 to 25 and 9 to 26 years**, respectively.* ***Females aged 9 to 13 years:** two doses are recommended at the interval of **0 and 6 months.*** ***Females aged 14 to 26 years:** three doses are recommended at the interval of **0, 1-2, 6 months.***									

Source: MOH, 2016 [9]

Footnotes: BCG = Bacillus Calmette-Guérin vaccine; HepB = Hepatitis B vaccine; DTaP = Paediatric diphtheria and tetanus toxoid and acellular pertussis vaccine; Tdap = Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine; IPV = Inactivated polio vaccine; OPV = Oral polio vaccine; Hib = *Haemophilus influenzae* type b vaccine; MMR = Measles, mumps, and rubella vaccine; PCV = Pneumococcal conjugate vaccine; HPV2 = Bivalent human papillomavirus vaccine; HPV4 = Quadrivalent human papillomavirus vaccine; ^ = Primary 5; D1/D2/D3 = 1st dose, 2nd dose, 3rd dose; B1/B2 =1st booster, 2nd booster; # 3rd dose of HepB can be given at the same time as the 3rd dose of DTaP, IPV, and Hib for the convenience of parents; ## 2nd dose of MMR can be given between 15-

Toxoids. In tetanus and diphtheria, the diseases are not directly caused by a bacterium itself, but by a toxin produced by the bacterium. For example, in tetanus, the symptoms are not caused by the *Clostridium tetani* bacterium, but by a neurotoxin it produces (tetanospasmin). Immunizations for this type of pathogen can be made by inactivating the toxin that causes disease symptoms. As with organisms or viruses used in killed or inactivated vaccines, this can be done via treatment with a chemical such as formalin, or by using heat or other methods.

Immunizations created using inactivated toxins are called *toxoids*. Toxoids can actually be considered killed or inactivated vaccines, but are sometimes given their own category to highlight the fact that they contain an inactivated toxin, and not an inactivated form of bacteria. Toxoid immunizations in both the U.S. and Singapore Recommended Childhood Immunization schedules have the tetanus and diphtheria immunizations and these are combined as DTaP.

Subunit and Conjugate Vaccines. Both subunit and conjugate vaccines contain only pieces of the pathogens they protect against. Subunit vaccines use only part of a target pathogen to provoke a response from the immune system. This may be done by isolating a specific protein from a pathogen and presenting it as an antigen on its own. The acellular pertussis vaccine and influenza vaccine (in shot form) are examples of subunit vaccines.

Herd immunity

With immunization, the numbers of individuals susceptible to disease are reduced. The number of people infected are also reduced and so there will be fewer sources of infection. And if there are fewer susceptible persons, then the viruses will be less able to spread. Hence, vaccines protects not only those who are vaccinated, but also indirectly those who cannot (the immunocompromised) or not vaccinated (e.g.new-borns, and those who reject

vaccinations). This is herd immunity effect. For most diseases, the herd immunity effect is achieved when the proportion of the population vaccinated is at least 90 percent[4].

IS THERE A MORAL RIGHT TO NONMEDICAL EXEMPTION?

1-Vaccine laws

Laws for vaccination requiring compliance to vaccinations against one or more dread infectious diseases are present in all countries. Legal obligations differ from country to country. Table 1 shows obligatory vaccinations in the EU, USA, and Singapore.[10]

Table 1. Obligatory vaccinations in the EU, USA, and Singapore

01	Belgium	Only Polio/OPV
02	Bulgaria	Adult/BCG/DTP/IPV/OPV/MMR/ DT/Td 3
03	Czech Republic	Adult/BCG/DTP/IPV/OPV/MMR/ DT/Td
04	France	BCG DT IPV
05	Hungary	BCG Hib DTaP IPV MMR HepB
06	Italy	DT/IPV/HepB
07	Latvia	BCG/DT/DTP/IPV/MMR//HepB/TBE/ Adults/Td
08	Poland	BCG/HepB/DT/IPV/OPV/MMR/PCV (since 2017)
09	Slovakia	DTwP/IPV/HiB/HepB/MMR/BCG/Td
10	Slovenia	DTaP/IPV/Hib/HepB/MMR/BCG
11	USA	Vaccination against: Diphtheria, Haemophilus influenzae type b, Measles, Mumps, Pertussis, Poliomyelitis, Rubella, Tetanus, Hepatitis B, Varicella
12	Singapore	**Diphtheria and Measles required by law; Rest are required for school entry: BCG, Pertussis, Tetanus, Poliomyelitis, Mumps, Rubella and Hepatitis B**

Source: Grzybowski et al, 2017; Singapore MOH, 2016

2-Exemptions

These can be:

- Medical exemptions for the immunocompromised and pregnant patients are acceptable exemptions because they cannot receive live attenuated vaccines;
- Religious exemptions; and
- Philosophical exemptions.

3-Arguments for and against exemptions

The arguments for and against removing religious and philosophical exemptions hinge on autonomy, utilitarianism, and the harm principle to protect the most vulnerable individuals.

Autonomy

Those who argue for autonomy will say that we are free to live our lives as we see fit. Also, parents are free to decide to raise their children in accordance with particular religious lifestyle, or in accordance to other lifestyle choices such as veganism.

Promoting public health: Utilitarianism

Utilitarianism is based on the ideology that actions are right to the extent that they produce the best consequences for the greatest number of people. There is the concept of act utilitarianism and the concept of rule utilitarianism. Act utilitarianism looks at the individual actions and considers which of the actions available to a person will have the best outcome. Rule utilitarianism looks at which rule if followed by all, will have the best outcome for society, even though the decision may make the individual slightly worse off. A good example following rule utilitarianism will be "Don't lie".

It is better off for society but in the short run may make the individual worse off. Public health interventions like vaccinations follows rule utilitarianism. Interventions are justified on the basis that it produces the best results for society at large – providing the greatest benefit for the greatest number of people. What would be the outcome if there is a conflict between individual and society's interest? If the harm is not big, then the individual can have the exemption, although it may have a bad consequence e.g. the resurgence of an infectious disease already under control.

The Disneyland measles outbreak in 2014-2015 was due to the consequence of allowing individual exemption from measles vaccination with the resulting drop of herd immunity below the protective level. Hence, in the longer run, a better ethical decision will be to accept vaccination for oneself or one's children rather than vaccine refusal based on the Harm Principle.

The Harm Principle: protecting the most vulnerable

The Harm Principle from John Stuart Mill's essay "On Liberty" says that the only justification for interfering with the liberty of an individual, against her will, is to prevent harm to others. The Harm Principle is used to justify various infectious diseases control interventions – including vaccinations.

The argument for vaccination is every increase in susceptible persons increase the risk of a breakdown of the herd immunity. Thus, when parents choose not to vaccinate their children, it puts the most vulnerable in the community at increased risk of contracting infectious diseases namely, the newborns, and the immunocompromised – people with cancer, those with one or more chronic diseases, and the elderly. Against this, the vaccine rejectors may argue that they or their children will suffer from the adverse effects of vaccines, and even say the vaccines may not be safe.

4-No moral right for non-medical vaccine exemption

Emhoff et all[5] asked if there is a moral right to non-medical vaccine exemption. They cited the Disneyland measles outbreak of 2014-2015 which infected a total of 121 susceptible persons as the case for rejecting no-medical exemptions. They argued that when herd immunity is at risk, any moral claim to exemption from vaccination on philosophical, or religious grounds are overridden.

VACCINE HESITANCY AND TRUST

1-Where do we go from here?

Ethical solution to vaccine refusal or hesitancy and the call for non-medical exemptions cannot be resolved merely by an ethical debate of autonomy, maleficence, beneficence, and justice. There is the need for a new ethical compact for engaging the vaccine rejectors. This consist of friendly engagement in promoting a correct understanding of what vaccines can do; evidence based correction of misconceptions; and maximization of opportunities to address the of concerns of vaccine safety[11].

2-Dealing with myths and misconceptions

Myths and misconceptions usually have grown from wrong information gathered from books, internet websites, popular literature, and chatting with friends. There is a need for good evidence based information to refute these myths. The following are 5 common myths where no evidence of the claims have been found[12]:

- DTP vaccines cause encephalitis
- MMR vaccines cause autism
- Thimerosal is toxic to the central nervous system
- Multiple vaccinations overwhelm the immune system
- Adjuvant ingredients in vaccines are unsafe – aluminum and formaldehyde.

Table 2 shows vaccine adverse reactions that may be encountered. They are self-limiting.

Table 2. Vaccine adverse reactions	
1	**MMR (live attenuated vaccine)** *Common:* local reactions, rash, and fever (days 7-14); *Rare:* thrombocytopenia (1:30,000), arthritis (temporary); *Extremely rare:* encephalitis, anaphylaxis (1:1 million)
2	**DTP** *Common:* local reactions, myalgia, and low-grade fevers; *Rare:* high fevers, uncontrollable crying, seizures (1:14,000); *Very rare:* anaphylaxis (1:1 million)
3	***Haemophilus influenzae* type B** *Common:* local reactions; *Rare:* fever over 101° F
4	**Gardasil (human papillomavirus)** *Common:* local reactions, painful injection; *Rare:* fainting, fever over 102° F
5	**Influenza injection** *Common:* local reactions, headache, myalgia; *Very rare:* anaphylaxis, Guillain-Barre syndrome (1 to 2:1 million)
6	**Hepatitis B** *Common:* mild local reactions; *Very rare:* anaphylaxis (1:1 million)
7	**Polio (IPV)** *Common:* local reactions; *Rare:* no known severe reactions to IPV
Source: Clift, Rizzolo, 2014 [12]	

3-Building trust on risk communication

There is a need that individuals who suffer from severe side effects of vaccinations can count on the government to take responsibility for such individuals affected by side effects. This is important for normative reasons namely, doing the right thing. A systematic way of reporting adverse events also give patients the confidence that their adverse events are being taken seriously. Additionally, by adopting such a new ethical perspective, the healthcare facilities concerned are likely to achieve and maintain trust[11].

PARENTAL VACCINE REFUSAL

1-Provider dismissal of vaccine-hesitant families

Some health care providers have adopted the policy of refusing to accept into their care families who refuse to vaccinate their children according to the country's national vaccination schedule. Whilst the frustration that have resulted in this policy is understandable on the part of providers, such a policy is misguided. It would not benefit the child or the health of the community, and might have a negative impact on both the child and the community. Physicians represent the best opportunities to influence the vaccine resistant parent, but may only succeed if the physicians are willing to continue to care for the children[13].

2-How should parental refusal be handled?

Just like handling vaccine refusal and vaccine hesitation in patients, the approach will be similar for parental concerns. There is a spectrum of anti-vaccine parents and they can be grouped into the following based on their actions taken towards vaccination tasks[14]:

- Vaccine rejecter – child not immunized, completely rejects vaccines, high safety concerns, lack trust in health care provider;
- Vaccine hesitant – under immunize child, delay and or question the vaccines being used, select only certain vaccines, desire trustworthy health care provider.

The actions of these two groups of parents can be compared to the actions of parents who are vaccine acceptors– child fully immunized, few concerns about vaccines, high trust in health care provider.

The hitherto accepted ethical perspective of focusing on the maleficence aspects of vaccine refusal and hence contributing to the decline of herd immunity does not address the ethical conflicts in such parents. They will be struggling with the ethical dilemma as parents of being party to a potentially harmful decisions by agreeing to vaccinate of their children. The new ethical perspective of treating these parents respectfully, addressing misconceptions respectfully and fully appreciating their concerns have a better potential for changing their current stand of vaccine refusal for their children.

Parental decisions are also influenced by various factors. Understanding the different types of factors can also help to pinpoint the areas of concerns. These factors can be grouped into:

- External factors – patient-provider relationship, school immunization requirements, collective values and social norms, policies, media;
- Vaccine-specific factors – perceived vaccine efficacy, perceived vaccine safety, perceived disease susceptibility
- Parent-specific factors – race/ethnicity, education level, income, knowledge about vaccines, past experiences.

3-The case of HPV

Human papillomavirus (HPV) remains the most commonly sexually transmitted infections in both males and females. There are two vaccines marketed:

- Gardiasil – quadrivalent vaccine – made up of 2 oncongenic viruses (HPV 16 and 18) and 2 wart causing viruses (HPV 6 and 11);
- Cervarix – made up of 2 oncogenic viruses (HPV 16 and 18).

The adoption of universal HPV vaccination has been difficult but appears to be increasing over time as public education improves.

For female patients, the cervical cancer prevention screening with vaccine administration remains superior to cervical cancer screening programmes employing Papanicolaou smears alone[15]. The risks of the vaccine are within the range of complications noted with other vaccination programmes.

There is no information whether inclusion of both males and females will induce additional herd immunity that ultimately protects a wider proportion of the population or not.

PUBLIC HEALTH EMERGENCIES: RATIONING, RESTRICTIONS, AND RESPONSIBILITIES

1-Rationing

All countries, regardless of their socio-economic status need to decide how to allocate scarce resources. A balance must be sought between utility – maximizing the common good and ensuring smooth economic and social functioning – and equality and fairness.

2-Restrictions

The fair distribution of limited vaccine supplies will require some prioritization, namely:

- those at greatest risk of infection: school children and health care workers, and
- the immunocompromised and chronic disease patients – likely to become ill if infected.

3-Responsibilities

- Parents' refusal to have their children vaccinated should be respected if the risk of disease is low or the disease is mild. However, if the risk of harm to the child is high, parental authority may be overruled to protect the child's best interests.
- Parents may not be around, and health care workers should be empowered to rapidly decide whether to vaccinate a child if done in the child and community's best interests.
- Emergency health care workers should be trained in ethics to improve their decision-making skills during acute humanitarian emergencies.

DISCUSSION

The introduction of vaccinations has greatly reduced mortality and morbidity from vaccine preventable infections in children, adults, and elderly people. Vaccination refusals have been in existence since the days of introduction of smallpox and the setting up of mandatory compliance. Over time the permission of exemptions in countries, notably the United States and some European countries, for non-medical reasons have reduced herd immunity to the extent of recurrence of childhood infections. Disneyland measles outbreak in 2014 and 2015 in California awakened United States and the world to the harm of non-medical exemptions for important vaccine preventable disease.

There is a need to address vaccine hesitancy and ethical aspects of risk communication that create trust. The ethical way forward is to stop treating vaccine sceptics as ill-informed or less educated persons and adopt a new ethical perspective of treating them respectfully. The new ethical perspective of addressing the misconceptions and concerns that vaccine sceptics may have has potential outcome of making them change their minds about vaccine refusal.

To build trust on the message of going for vaccination, there is a need that individuals who suffer from side effects of vaccinations can count on the government to take responsibility for such individuals affected by side effects. This is important for normative reasons namely, doing the right thing. Additionally, by adopting such a new ethical perspective, the government is likely to contribute to restored and maintained trust.

Parental refusal in the same way should be handled with the new ethical perspective of treating them respectfully and be focused on addressing the misconceptions and concerns that they may have about the potential of vaccinations harming their children.

With regards to ethical dilemmas in emergency situations, there is a need to address the issue from the standpoint of vaccine supply issues or mandate issues. To deal with supply issues, the ethics of distributive justice in rationing and restriction should apply. To deal with vaccine refusal, the new ethical perspective of handling individuals with ethical dilemmas respectfully highlighting the importance of responsibility (duty) has much to recommend as an ethical strategy.

CONCLUSIONS

- Vaccinations are effective solutions of controlling vaccine preventable infections. However, like any medication, they have the potential of causing minor adverse effects.
- Also, such adverse effects may be blown out of proportion if the myths and misconceptions remain unchallenged with evidenced information. The result will be a growing distrust to anyone advocating vaccination.
- The new ethical strategy is to deal with vaccine rejecter and vaccine hesitant respectfully. It is ethically incorrect to view vaccine sceptics as ill-informed or less educated individuals.
- By maximizing the opportunities for engagement and discussion of patient or parental vaccine concerns, the potential for a change in decision making towards vaccine acceptance is big.
- In acute humanitarian emergencies - the 3 Rs – rationing, restrictions, and responsibilities – provide a framework for rapid correct ethical decision making.

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LEARNING POINTS

- **Vaccinations are effective solutions of controlling vaccine preventable infections.**
- **With the control of vaccine preventable dread infections, the community focus may shift to vaccine safety and vaccine refusals**
- **The myths and misconceptions of vaccination should not remain unchallenged with evidenced information.**
- **The new ethical strategy is to deal with vaccine rejecter and vaccine hesitant respectfully. It is ethically incorrect to view vaccine sceptics as ill-informed or less educated individuals.**
- **By maximizing the opportunities for engagement and discussion of patient or parental vaccine concerns, the potential for a change in decision making towards vaccine acceptance is big.**
- **In acute humanitarian emergencies - the 3 Rs – rationing, restrictions, and responsibilities – provide a framework for rapid correct ethical decision making.**