IV.3.4 Xenotransplantation

F.J. van Ittersum – W.J. Eijk

Xenotransplantation concerns the transplantation of an organ or tissue of a given type of animal to another type of animal or to a human being. This type of transplantation has gained interest because of the shortage of human organ donations. At the end of the 20th century there was great enthusiasm about xenotransplantation, especially because of a few noted successes: a Chimpanzee kidney was only rejected after nine months, and a Baboon heart was rejected in a human baby after a few weeks. In general, those successes were limited and the enthusiasm had dwindled at the beginning of the 21st century [1: G. Blancho. Editorial xenotransplantation. Curr Opin Organ Transplant. 2009/03/21 ed 2009, 14, 147 doi:10.1097/MOT.0b013e3283292595.]. In particular, the exposure of immunogenic antigens on the animal donor tissue was found to elicit more rejection reactions than hoped for. These rejection reactions were also found to be less easily treated than when the organs came from human donors. Getting this problem under control was, however, a prerequisite for obtaining a usable graft survival. The chosen solution direction involved the genetic modification of donors, mostly pigs [2: D.K.C. Cooper, R. Gaston, D. Eckhoff, J. Ladowski, T. Yamamoto, L. Wang, H. Iwase, H. Hara, M. Tector and A.J. Tector. Xenotransplantation-the current status and prospects. Br Med Bull. 2017/12/12 ed 2018, 125, 5-14 doi:10.1093/bmb/ldx043.] Genetic modification has been easier since 2014 with the introduction of the CRISPR-cas9 technique. The first human xenotransplantation successes were expected with transplantation of genetically modified cells derived from pig islets of Langerhans. [3: D.K.C. Cooper, R. Gaston, D. Eckhoff, J. Ladowski, T. Yamamoto, L. Wang, H. Iwase, H. Hara, M. Tector and A.J. Tector. Xenotransplantation-the current status and prospects. Br Med Bull. 2017/12/12 ed 2018, 125, 5-14 doi:10.1093/bmb/ldx043.] In 2022, however, a man in Maryland (USA) received a heart from a cloned pig in which 10 genes had been modified. [4: B.P. Griffith, C.E. Goerlich, A.K. Singh, M. Rothblatt, C.L. Lau, A. Shah, M. Lorber, A. Grazioli, K.K. Saharia, S.N. Hong, S.M. Joseph, D. Ayares and M.M. Mohiuddin. Genetically Modified Porcine-to-Human Cardiac Xenotransplantation. N Engl J Med. 2022/06/23 ed 2022, 387, 35-44 doi:10.1056/NEJMoa2201422.] The initial course was prosperous. After 49 days, severe thickening of the heart muscle developed; 60 days after transplantation, the patient died. At autopsy, necrosis (death) of cardiac myocytes was seen. The cause was multifactorial: rejection, an immune response to the administered human immunoglobulins and activation of porcine CMV virus. [5: M.M. Mohiuddin, A.K. Singh, L. Scobie, C.E. Goerlich, A. Grazioli, K. Saharia, C. Crossan, A. Burke, C. Drachenberg, C. Oguz, T. Zhang, B. Lewis, A. Hershfeld, F. Sentz, I. Tatarov, S. Mudd, G. Braileanu, K. Rice, J.F. Paolini, K. Bondensgaard, T. Vaught, K. Kuravi, L. Sorrells, A. Dandro, D. Ayares, C. Lau and B.P. Griffith. Graft dysfunction in compassionate use of genetically engineered pig-to-human cardiac xenotransplantation: a case report. Lancet. 20230629 ed 2023, 402, 397-410 doi:10.1016/S0140-6736(23)00775-4.] In 2023, a kidney from the same genetically modified pig species remained functioning properly for a week in a brain-dead patient with renal insufficiency. After a week, support (including ventilation) of the brain-dead patient was discontinued. The kidney transplant was functioning very well at that time and no signs of rejection were visible under the microscope either. [6: J.E. Locke, V. Kumar, D. Anderson and P.M. Porrett. Normal Graft Function After Pig-to-Human Kidney Xenotransplant. JAMA Surg. 20230816 ed 2023 doi:10.1001/jamasurg.2023.2774.] This result possibly means that xenotransplantation with organs from genetically modified animals has moved closer to application in humans.

In addition, in xenotransplantation, the transmission of animal viruses to human beings proves to be a clear risk [7: L. Scobie and Y. Takeuchi. Porcine endogenous retrovirus and other viruses in xenotransplantation. Curr Opin Organ Transplant. 2009/05/27 ed 2009, 14, 175-179 doi:10.1097/mot.0b013e328327984d.]. Also with regard to

this problem, genetic modification using the CRISPR-cas9 technique is hoped to move forward: viruses present in DNA could be “cut” out of the DNA using this technique. The genetically modified pigs used in 2022 and 2023 would not carry the porcine endogenous retrovirus. Nevertheless, the porcine-CMV virus appeared to be transmitted and less treatable than the human equivalent. [8: B.P. Griffith, C.E. Goerlich, A.K. Singh, M. Rothblatt, C.L. Lau, A. Shah, M. Lorber, A. Grazioli, K.K. Saharia, S.N. Hong, S.M. Joseph, D. Ayares and M.M. Mohiuddin. Genetically Modified Porcine-to-Human Cardiac Xenotransplantation. N Engl J Med. 2022/06/23 ed 2022, 387, 35-44 doi:10.1056/NEJMoa2201422.]

In 2001, the Pontifical Academy for Life dedicated a symposium to this subject, in order to respond to a number of questions of a moral nature with respect to xenotransplantation. The symposium highlighted, first of all, three anthropological and ethical issues relevant to the question of whether xenotransplantation, as such, is a good act [9: Pontifical Academy for Life. Prospects for xenotransplantation scientific aspects and ethical considerations. Vatican City 2001.]:

1. The acceptability of human intervention in the created order.
2. The ethical acceptability of using animals to increase the Medical Care for Life: Therapeutic Interventionchance of survival of human beings and to increase their wellbeing.
3. The possible objective and subjective influence which an organ or tissue of animal origin can have on the identity of the human recipient.

3.4.1 The acceptability of intervention in the order of creation

According to the created order, man, created in God’s image and likeness, has a central place. The lower creatures serve man, and he has a limited right of disposal over them. The purpose of this central position of man is not so much his lordship over other creatures, but his cooperation with the Creator in fulfilling the purpose of creation: “Be fruitful and multiply, and fill the earth and subdue it” (Gen 1:28). The “creatures which are lower in the order of creation” must serve and be subservient to this particular task. In this light, xenotransplantation is acceptable.

3.4.1.1 The use of animals for man

In virtue of their being created beings, animals have their own worth, which man must value and respect. God placed the animals, together with other non-human creatures, at the service of man. Still, they, too, are God’s creatures, and it is, therefore, important, in the use of animals, to be alert as to whether there is a necessity for doing so and whether the chosen use does not cause the animal unnecessary suffering.

3.4.1.2 The influence on the identity of the recipient

As explained earlier, it is morally wrong to implant a foreign organ which changes the identity of the person [10: S. Ioannes Paulus II. Ad eos qui conventui de chirurgicis transplantationibus interfuerunt (29-8-2000). Acta Apostolicae Sedis 2000, 92, 822-828.] [11: Pius XII. Vous nous avez demandé. Toespraak tot de Italiaanse Vereniging van hoornvliesdonors en de Italiaanse bond van blinden en tot oogspecialisten, over de morele waardering van de hoornvliestransplantatie (14 mei 1956). Acta Apostolicae Sedis, Rome: Libreria Editrice Vaticana; 1956, 48.] [12: Pontifical Academy for Life. Prospects for xenotransplantation scientific aspects and ethical considerations. Vatican City 2001.]. This issue does not arise in the transplantation of a heart, kidney or liver. Brains and genital organs, however, are inseparably united to the identity of the human person (cf. the present Chapter 3.5). Given the effect of the transplantation of the organs mentioned on the identity of the person, they are not permitted.

In conclusion, as long as the identity of the human recipient is not affected, xenotransplantation is acceptable, as long as the risks are proportionate, which, as will become evident later, turns out to be a great difficulty [13: Pontifical Academy for Life. Prospects for xenotransplantation scientific aspects and ethical considerations. Vatican City 2001.].

There are, however, a number of aspects which require more attention:

1. The risks to the recipient.
2. The use of organs and tissues derived from transgenic animals.
3. The allocation of the healthcare means.
4. The patentability in xenotransplantation

3.4.2 The health risk to the recipient

A number of risks are already evident. First, there is the chance of rejection. At present, this chance is high and the suppression of the immune system will therefore have to be more radical. It is certain that the recipient has a high chance of physical and mental damage from the rejection as such, as well as from the immunosuppressive therapy. One also fears that xenotransplantation can cause animal viruses to be transmitted to human recipients. The risks of transmission of the Porcine Endogenous Retrovirus (PERV) and Hepatitis E (HEv) are not fully clear [14: L. Scobie and Y. Takeuchi. Porcine endogenous retrovirus and other viruses in xenotransplantation. Curr Opin Organ Transplant. 2009/05/27 ed 2009, 14, 175-179 doi:10.1097/mot.0b013e328327984d.]. No transmission of these viruses was observed in initial studies of humans who had had contact with pig tissues or studies in which pig tissues were transplanted to non-human primates (monkeys) [15: D.K.C. Cooper, R. Gaston, D. Eckhoff, J. Ladowski, T. Yamamoto, L. Wang, H. Iwase, H. Hara, M. Tector and A.J. Tector. Xenotransplantation-the current status and prospects. Br Med Bull. 2017/12/12 ed 2018, 125, 5-14 doi:10.1093/bmb/ldx043.]. However, to completely avoid the problem of virus transmission, good practices regarding selection of not severely infected animals and possibly genetic modification of these animals still need to be developed.

3.4.3 Transgenesis

In order to optimise the chance of survival of organs in human beings, the genetic modification of the potential animal-donors seems to be an obvious option. The donor pigs used in 2022 and 2023 were genetically modified with 3 knockouts and 7 gene modifications, which would reduce the organs' rejection reactions after transplantation. The changing of the genetic make-up of animals is acceptable as long as a number of ethical principles are taken into consideration:

1. The changes resulting from the genetic modifications may not cause the animal pain, fear, and suffering.
2. The effects on the offspring of the human recipient and the environment must be taken into consideration.
3. Transgenic animals must be well-controlled and may not just be set free in the environment.
4. The number of transgenic animals which is brought into being for the purpose of transplantation must be kept to a minimum.
5. The removal of organs and/or tissue must be carried out in one single surgery.

6. Every experiment must be judged by a competent ethical commission.
   It is also important that recipients are fully informed about the origin of the organs and the accompanying risks and that one obtain from the recipients an informed consent for the procedure (Pontifical Academy for Life 2001, no. 15-16) [16: Pontifical Academy for Life. Prospects for xenotransplantation scientific aspects and ethical considerations. Vatican City 2001.].

Not all Catholic ethicists, though, agree with this point of view of the Pontifical Academy for Life. [17: N. Tonti-Filippini, J.I. Fleming, G.K. Pike and R. Campbell. Ethics and Human-Animal Transgenesis. National Catholic Bioethics Quarterly 2006, 6, 689–704.] Tonti-Filippini, Fleming, Pike and Campbell are opposed to the intentional mixing of human DNA with that of animals.

1. In the first place they read a prohibition not only of hybridisation in the sense of fertilisation between human and animal gametes, but of any human-animal transgenesis in Donum Vitae (I,6). [18: Congregatio pro Doctrina Fidei. Donum Vitae. Instructio de observantia erga vitam humanam nascentem deque procreationis dignitate tuenda. Acta Apostolicae Sedis 1988, 80, 70-102.] They are of the opinion that the term ‘hybrid’ does not only mean an organism having its origin in a fertilisation process, but any organism of which its inherited characteristics stem from organisms of different species. Therefore, the Congregation for the Doctrine of the Faith would condemn in its instruction Donum Vitae apart from hybridisation by means of fertilisation of human and animal gametes every form of human-animal transgenesis.
2. Secondly, they are convinced that human-animal transgenesis of whatever proportion, also in the case of the transmission of one human gene to an animal ovum or zygote, causes an unacceptable confusion of identity.

A hybrid resulting from fertilisation of a human and an animal gamete has a full set of genes from human origin. Even if it would become a full-grown individual without specific human features as rational capacities and the capacity of free decision making, one could not by all means exclude that it is animated by a human soul and hence a human person. For the presence of the full set of genes from the animal part could prevent the spiritual faculties from coming to expression. It is of course impossible to say which proportion of human-animal transgenesis would result in an organism with the ‘disposition of the material’ (see this Manual II.1.1.2.4) to be animated by a human soul. The Pontifical Academy obviously supposes that this is not the case when only one or a few human genes, especially those which might prevent a immunological rejection of an organ from the resulting organism after transplantation to humans, are added to the genome of an animal ovum or zygote, and that this is therefore morally licit. However, it is a fact that not all Catholic ethicists share this view. Tonti-Filippini, Fleming, et al. think that “the confusion of identity arises as soon as any human genes become formative of the new being” [19: N. Tonti-Filippini, J.I. Fleming, G.K. Pike and R. Campbell. Ethics and Human-Animal Transgenesis. National Catholic Bioethics Quarterly 2006, 6, 689–704.] and that the transmission of only one human gene to an animal ovum or zygote is an infringement on human dignity and an abuse of the human generative faculties (they do however not reject adding human genes to bacteria, because these cannot develop into embryos, such that no confusion of identity will arise).

3.4.4 Allocation of healthcare resources

The development and implementation of xenotransplantation demands the investment of some of the resources available for healthcare. These resources, when invested in xenotransplantation, cannot be used for other purposes in healthcare. A thorough analysis of costs and benefits is therefore inevitable [20: Pontifical Academy for Life. Prospects for xenotransplantation scientific aspects and ethical considerations. Vatican City 2001.].

3.4.5 Patentability

Without doubt, private companies have invested much money and energy in the development of xenotransplantation. The application for a patent is therefore a logical step for such companies. Patents, however, lead to higher costs for the consumers, in comparison to non-patented products. Even though there is no moral objection to patents, as such, it is important to guarantee that the recipients will have equal access to healthcare, without any form of discrimination and impediments based on higher costs [21: Pontifical Academy for Life. Prospects for xenotransplantation scientific aspects and ethical considerations. Vatican City 2001.].

IV.1 Diagnostics, prevention, therapy and rehabilitation

F.J. van Ittersum – W.J. Eijk

Introduction

1. How are medical decisions taken?
2. The acceptance of the burden, pain and discomfort of diagnostic procedures and of preventive and curative treatments
3. The acceptability of side-effects and complications of diagnostic procedures, and of preventive and curative treatments
4. Diagnostics of possible ailments and of predisposition for illnesses
5. Preventive medicine

IV.1.5 Preventive Medicine

F.J. van Ittersum – W.J. Eijk

F.J. van Ittersum and L.J.M. Hendriks

1.5.1 Preventive diagnostics and preventive treatment

1.5.1.1 Shift from emphasis on therapeutic to preventive medicine in the 20th

century

In the second half of the 20th century, the focus in medicine shifted more towards prevention and early detection of diseases, even though much of the attention of doctors and nurses is still on curing diseases or conditions and alleviating their symptoms. Examples of disease prevention include taking hygienic measures to prevent the spread of infectious diseases, vaccinations to drastically reduce the irreversible complications of infectious diseases in particular, treatment of mildly elevated blood glucose levels, mildly elevated blood pressure levels or cholesterol levels to reduce the development of cardiovascular disease in the long term. Giving lifestyle advice such as quitting smoking or limiting alcohol consumption also falls under preventive medicine. Examples of early disease detection in the Netherlands are, first of all, the ongoing population screening programmes: cervical carcinoma (cervical cancer), mammary carcinoma (breast cancer) and colon carcinoma (colorectal cancer). In addition, there are specific risk groups that are screened for the presence of certain conditions, especially people with relatives with genetically determined conditions.

Those who undergo preventive screening or receive preventive lifestyle advice or treatment almost never have symptoms of the condition that prevention is targeting, but are hopefully either treated at an earlier stage, increasing their chances of being cured, or are saved from permanent disease symptoms or physical or mental disabilities in the future.

Although difficult to prove, it is plausible that the aforementioned forms of preventive medicine in the 20th century contributed significantly to the increase in life expectancy that occurred during that period. The decline in tuberculosis cases is mainly due to improved hygiene and living conditions and not to the introduction of tuberculostatics, antibiotics that can be used to fight the Mycobacterium tuberculosis bacilli; the decline in Cardiovascular Accidents (CVAs, strokes) is partly due to better treatment of asymptomatic hypertension. Also, much can be expected from the decline in smoking rates on the number of people who develop Chronic Obstructive Pulmonary Disease (COPD, formerly emphysema) or lung cancer. Because these diseases can still occur many years after smoking cessation, the maximum benefit of this has yet to be achieved.

In prevention, not all examined (screened) or treated individuals achieve gains from preventive measures or treatments. Not every woman who has a smear test ever gets a cervical carcinoma, not everyone with long-term hypertension gets a CVA. Thus, a certain number of people will need to be screened or treated in order to diagnose disease in one person or, in the case of treatment, prevent a complication. In epidemiology, these numbers are known as Number Needed to Screen (NNS) and Number Needed to Treat (NNT). For example, to prevent one case of cervical carcinoma, 2560 women had to have a smear taken in the year 2000: the NNS is then 2560. If over 5 years 100 people need to be treated for hypertension to prevent one CVA, the NNT over 5 years is 100.

NNS and NNT thus say something about the effectiveness of screening and preventive treatment, respectively, and thus something about the costs. In the case of an NNS or NNT of 20, the costs of screening or preventive treatment in relation to the one case detected or prevented are much lower than if the NNS or NNT had been 1000. Of course, the costs still depend on the price of one screening test or one preventive treatment. It is the cost of laboratory or X-ray tests or the cost of using blood pressure-lowering drugs over the number of years of the NNT.

NNS and NNT together with the cost of screening or treatment of a single person determine the financial burden that a prevention programme places on society.

1.5.1.2 Ethical analysis of preventive medicine

Roman Catholic morality itself does not distinguish between the ethical assessment of treating pre-existing diseases or that of preventing them. Prevention of disease is part of man's duty to take care of his health. In this sense, it can be seen as a variant of treat . The limited providence that man has as a free and reasonable being requires him to take responsibility, to the best of his ability, for the prevention of diseases that he might contract in the future (this fact is elaborated on in paragraph 2.3 of this section). What is essential is that the preventive act in itself is morally justified and that medicines or vaccines used for this purpose have in principle been produced in a morally responsible manner. Since preventive medicine, like therapeutic medicine, aims to protect the life and/or health of the human person as a whole, it can be legitimised – to the extent that it affects bodily integrity – on the basis of the therapeutic principle (see Chapter I.2.2.3).

In addition, preventive medicine involves socio-ethical considerations. Money spent on preventive medicine cannot be spent on other collective expenditures such as those on education, infrastructure or support for the weak in society. Therefore, the cost of preventive treatments requires social and political consideration. The common good (Chapter VII, Introduction) and the principles of sociality and solidarity (see Chapter I.2.2.5) require that prevention programmes should be available to all who can benefit from them, regardless of their financial means.

In countries where healthcare is largely collectively funded, the (financial) burden that preventive health programmes place on society must be taken into account. This requires economic analyses of preventive programmes. Conclusions from such analyses are straightforward and unambiguous if a prevention programme turns out to be cheaper than the costs of treating diseases and conditions and their consequences, including those of the relevant treatments, hospital admissions and admissions to nursing homes. As already explained in Chapter VI.1.1.1, the results of economic analyses fall unfavourably if many people die without the application of prevention measures, while when they are applied, many people survive. When more people survive, it often costs society more than when they die, because, as a consequence, people with multiple pathology often stay alive, whose treatment entails high costs for society. Incidentally, this can also occur when people are cured by treatment of a disease and/or do not die from it, but curing or preserving life through therapeutic intervention is generally more easily perceived as a good thing. One tries to weigh the extra costs that will be incurred by the prevention programme against the survival gain and quality of life (well-being) in this gained life time through the QALY (see Chapter VI.1.1.1). However, the QALY does not appear to be an adequate measure to capture the ratio between the costs of prevention programmes on the one hand and those of survival gain and quality of life during the life years gained from them on the other. The Dutch Raad voor de Volkgezondheid en Zorg (Council for Public Health and Care) , therefore, recommended including the burden of disease of a disease or condition in addition to the QALY: in this opinion, on a scale of 0 to 1, chalk nails would represent a very low burden of disease (0.02), whereas a non-Hodgkin lymphoma would represent a high burden of disease (0.97). When this disease burden thus quantified is taken into account, a QALY might cost €10,000 to €80,000 in the Netherlands. For vaccination, one uses a QALY cost of €20,000.

However many difficulties these analyses may have, they can be helpful in guiding or reducing the price of diagnostic tests or preventive treatments (drugs or vaccines). Producers of laboratory tests, drugs and vaccines often try to make large profits on their new, usually patented products: an economic analysis can provide insight into the costs of producing preventive agents on the one hand, and the costs that might be saved if they prevent a disease, the treatment of which might also entail the necessary costs, on the other. This played a role in negotiating the price of the HPV vaccine. Altogether, economic analyses can be helpful in a choice for or against a prevention programme: much of the trade-offs will continue to depend on the prudence of the

responsible administrators.

In non-Western European societies, including the United States, access to healthcare is not readily available to all. This also applies to prevention programmes. This goes against the demands of the common good and against the principles of sociality and solidarity.

1.5.2 Vaccination

1.5.2.1 Mode of action and effectiveness of vaccination

Vaccination is the administration of small quantities of an attenuated or inactivated, basically pathogenic, micro-organism (bacteria or virus) or their fragments with the aim of protecting people or animals from the diseases caused by these micro-organisms as a precautionary measure. Vaccines are usually administered by subcutaneous or intramuscular injection, but there are also oral forms of administration. The action of vaccinations is based on two principles. First, the person receiving the vaccine develops an immune response against vaccine antigens. In classical vaccines, these antigens are actually in the injected fluid. In RNA, DNA and vector vaccines, these antigens are made by body cells of the person receiving the vaccine. Usually, IgM and IgG antibodies are produced as a result. In addition, specific T-memory cells develop, which will then remain present in lymph nodes or bone marrow for a long period of time. When the antigen next enters the body, it is either neutralised by the antibodies present in the blood or the activation of T-memory cells results in an accelerated, new production of IgG antibodies or other lymphocytes appear in the bloodstream to inactivate the microorganism. Thus, the vaccinated individual is first of all protected by the vaccination itself against the disease targeted by the vaccine.

Whether vaccination is effective depends largely on the so-called “vaccination coverage” in the population. If a significant proportion of the population is vaccinated against a particular disease, a bacterium or virus may be more difficult to spread among humans or animals. After all, in a vaccinated individual, a bacterium or virus is quickly rendered harmless by the circulating antibodies or the accelerated immune response. For further spread to other humans, it would have been necessary for the microorganism to have been able to multiply to some extent in the host, even if the host itself was not affected. After this multiplication, the microorganism would be transmitted to another individual via water droplets (spread via coughing or sneezing) or via blood or other body fluids (mucus, semen). After a successful vaccination, microorganisms do not manage to multiply or multiply less well in a host. A high vaccination rate therefore benefits others. These are of course those who have consciously decided not to be vaccinated, but also those who have not (yet) been vaccinated, those who are weakened by e.g. old age or illnesses associated with reduced immune defence or illnesses requiring treatment with immunosuppressive drugs. At what vaccination rate among the population the said protection of the unvaccinated occurs depends strictly on the disease. Nevertheless, the World Health Organisation (WHO) uses a target vaccination rate of 95% for almost all diseases for which vaccination is used. In the Netherlands, vaccination rates for DTP (diphtheria, tetanus and polio) and MMR (mumps, measles and rubella) had dropped to 90.0% and 90.1% respectively in 2017. . In 2018, these values were 92.4 and 92.9%, respectively. It is too early to conclude from this that the Netherlands is back on track to restore the required vaccination coverage.

1.5.2.2 Side effects and safety of vaccination

Because a vaccine contains weakened or inactivated bacteria or viruses and adjuvants that do not occur naturally in the body, vaccination can have side effects. Common side effects include redness at the injection site (>10% of cases), fever, headache, swelling of a limb where the vaccine was injected (1-10% of cases) and crying in babies. In addition, allergic reactions such as skin rashes all over the body and itching may occur. There are also specific side effects of certain vaccinations. For example, after MMR (mumps, measles, rubella) vaccination, a temporary deficiency of platelets occurs in 1:20000 children.

On the occurrence of very severe allergic reactions and side effects, such as anaphylactic shock, breathing difficulties or even death, there is a difference of opinion in the Netherlands. The Lareb side effects centre reports annually on side effects of vaccinations. More serious events, which are seen on websites of, for example, the Nederlandse Vereniging Kritisch Prikken (NVKP; Dutch Association for Critical Prickings) as adverse reactions to vaccinations, have not been reported to Lareb or, according to Lareb, cannot reasonably be considered to be due to the administration of the vaccine.

One topic of debate is whether autism could be a complication of MMR vaccination. There has been confusion about this in the recent past. The journal The Lancet published a study in 1998 linking the MMR vaccine with the incidence of nonspecific colitis and autism. In the UK, MMR vaccination coverage dropped remarkably after this publication. The Lancet retracted the article in 2010 due to conflict of interest and fraud by authors. Another study linking MMR vaccination and autism was also retracted by a journal due to unsound methodology. On its website, however, the NVKP endorses the conclusions of the retracted article in The Lancet and accuses those who want to prove that there is no link between MMR and autism of conflict of interest and fraud. It goes on to cite an epidemiological study purporting to show that the incidence of autism among people born from 1998 onwards, the year in which the MMR vaccination rate fell as a result of the above-mentioned publication in The Lancet, was much lower than before, and then gradually rose again among people born from 2000 onwards. Such an observation is certainly striking, but not evidence of a causal relationship between MMR vaccination and autism. In any case, what this discussion shows is that there is an ongoing uncertainty with regard to interpreting and weighing results of scientific research and that the objectivity of scientists' conclusions, even when they enjoy a good reputation as such, is not beyond doubt.

The (alleged) side effects are mainly a reason for group of highly educated people to oppose vaccination. The first and most important reason for them is the lack of sense of urgency, due to the fact that, as a result of the long-term high vaccination coverage, outbreaks of certain diseases have hardly occurred in the Netherlands for a long time. But secondly, paradoxically, it probably also plays a role that precisely highly educated people will delve into the side effects that might exist, question the information about vaccination provided by government bodies and researchers, and interpret the available data – rightly or wrongly – differently from scientists.

Side effects of the vaccines have also been reported in the extensive vaccination programmes against SARS-CoV-2. In general, these were mild side effects, such as short-term malaise, fever or pain in the arm where the injection was given. Rare but serious side effects also appeared to occur: the Astra-Zeneca vaccine and (to a lesser extent) the Janssen vaccine have been associated with thrombosis with thrombocytopenia syndrome, a condition in which both thrombosis and a low platelet count are observed. The Pfizer vaccine is associated with myocarditis (inflammation of the heart muscle).

1.5.2.3 Ethical analysis

Some members of Orthodox Protestant denominations oppose the prevention of disease by vaccination for religious reasons . They base this rejection on Jesus' words in Matthew 9.12: "It is not the healthy who need a doctor, but the sick" (cf. Luke 5.31; Mark 2.17). This would imply that one should use medical treatment only when suffering from a current condition, but should not do so when healthy, only for the purpose of preventing an illness. However, Jesus only says that the sick need a doctor, to make it clear why he goes among sinners (the 'sick'), but does not speak at all about the prevention of illness in this context. By disease here is meant spiritual illness, sin . Furthermore, some Orthodox Protestants base their rejection of disease prevention on the definition of Divine Providence according to question 27 of Sunday 10 of the Heidelberg Catechism: "The omnipotent and omnipresent power of God, by which He maintains heaven and earth, together with all creatures, even as with His hand yet, and so governs, that foliage and grass, rain and drought, fruitful and unfruitful years, food and drink, health and infirmity, riches and poverty, and all things, do not come to us by chance, but from His Fatherly hand. " This definition implies, among other things, that health and sickness come to us not by chance but by God's hand. For this reason, man should not prevent an impairment of his health by non-ordinary means, such as vaccination, because that would imply opposition to God's judgement. However, once affected by a disease, one should be allowed to make use of medical treatment on the basis of the text from Matthew 9:12 quoted above. At most, one may use ordinary means to prevent disease, such as sanitary measures. This position came under severe criticism when epidemics of poliomyelitis broke out in some Dutch villages in 1971 and 1978. The latter epidemic affected 110 people, all Orthodox Protestant, who had not been vaccinated: one of them died, while only a few suffered long-term or lifelong paralyses (the orthodox Protestants referred to do not share the aforementioned rejection of preventive medicine, by the way).

In addition, there is group of people who reject vaccination not for religious reasons, but because they dislike artificial intervention in man's nature, such as people who place great value on homeopathy. They reject vaccines because, as artificially manufactured substances, they are not peculiar to the human body or at least contain substances that do not occur naturally in the human body. The fact that vaccines are administered when a person is generally still healthy reinforces their resistance to vaccination. Similar views can be found among adherents of the anthroposophical view of man, who want to leave it to man's nature to protect himself from disease. The view that the fight against disease should be left entirely to nature itself does not do justice to medicine, which uses what is available in nature to develop and prepare medicines and perform surgical procedures by means of rational knowledge (obtained, incidentally, by using man's natural intellectual faculties).

The Roman Catholic Church and the vast majority of Protestants give a different interpretation of God's Providence. God created man in his image and likeness. As a result, man has the ability to think and the ability to act freely within a certain space. This means that man has a degree of providence, a reflection of God's Providence. It is therefore inherent in God's Providence that man has a providence – albeit limited. This providence creates obligations. Man cannot only prevent diseases, but must do so to the best of his ability. Having oneself vaccinated or one's children vaccinated is therefore a morally good act. Side effects can be accepted on the basis of the principle of the double-effect act, because the intended effect (immunisation) is not achieved through the collateral effect and there is a proportionally serious reason to accept these side effects (see Principles of Medical Ethics, Chapter I.2.2.1 and Chapter VI.3.2.) In the 2020-2021 COVID pandemic, the trade-off of the proportionality of the two effects of vaccination fell in favour of vaccination: the intended benefit (immunisation of the population) far outweighed the rare occurrence of side effects.

Also, the human person is essentially a social being. From this flows the principle of sociality and solidarity

(Chapter I.2.2.5). The limited degree of providence we have implies that we bear responsibility not only for our own health but also for that of fellow human beings. When we vaccinate ourselves and parents vaccinate their children, we contribute to making infectious diseases less easily spread. Our own vaccination and the vaccination of children can prevent others who are not vaccinated, children under the vaccination age or people who do not get vaccinated for reasons of principle from contracting infectious diseases. This is a contribution to the common good.

For these reasons, vaccination is not only a moral good for the individual, but also for the common good.

Besides the fact that the use of preventive medicine is permissible and often a duty, there are some ethical aspects that deserve further attention. Vaccination – however limited – involves violating the integrity of the body, usually through penetration of the skin for the injection of the vaccine itself and then the subcutaneous or intramuscular injection of the foreign body material for the sake of preventing disease. As stated in the introduction to this section, there is no difference between treatment or prevention of disease in terms of moral assessment. To preventive medicine, therefore, as noted earlier, the totality principle or therapeutic principle also applies (Chapter I.2.2.3). This principle implies that interventions in the human body aimed at preserving the life or health of the human person as a whole can be justified, provided its functional integrity remains intact. As vaccination at most affects anatomical integrity to a negligible extent and can prevent the threat to life or health from the possible future contracting of a disease, vaccination can therefore be legitimised on the basis of the therapeutic principle.

Other difficulties lie in the questions of whether vaccines are safe, whether this safety has been established according to current scientific methods and whether vaccines have been produced in morally responsible ways. In particular, given the aforementioned discussion about the possible relationship between MMR vaccination and the occurrence of non-specific colitis and autism, there is an obvious requirement that scientists must act honestly and objectively, without conflicts of interest. While side effects occur, the risks are certainly proportionate to the good effect they work. One of the bigger problems in discussions about vaccination Western European media in 2018-2019 concerned the fact that opposition to vaccination was very often not based on scientific data. As indicated above, serious side effects, such as paralysis, autism or increased risk of cancer, are invoked as a motive to refrain from vaccination, but these side effects are usually not or hardly reported and documented or conclusively established. They have unfortunately become a major factor in discussions about vaccinations as ‘fake news’ and incorrect or unsubtle messages are repeated over and over again on social media. It is difficult to resist this massive disinformation. The major media attention generated by the medical profession and politicians to increase vaccination coverage focuses mainly on refuting this disinformation.

When preparing vaccines containing attenuated or inactivated microorganisms, the bacteria and viruses that are the basis for vaccines must be grown on a nutrient medium. Viruses require live cells for this purpose. These are often cell lines, cells that were once, often years ago, obtained from a human or animal and then grown on in the laboratory. So new human or animal donors are not needed all the time to have these cells available. The source of the cells is different for different vaccines. For the vaccines against mumps and measles, the cells used are derived from a chicken embryo, vaccines against influenza and yellow fever are produced on incubated chicken eggs, the vaccine against human papillomavirus (HPV, the causative agent of cervical cancer) on cells from Trichoplusia ni, a species of moth. There are four cell lines derived from human, aborted foetuses: the Medical Research Council cell strain 5 (MRC-5), derived from connective tissue cells from lung tissue of a 14-week-old foetus aborted in 1966, the WI-38 cell line, also derived from connective tissue cells from lung tissue, this time from a 3-month-old male foetus aborted in 1960, the HEK293 cell line, derived from kidney tissue of a

foetus aborted in 1973 in the Netherlands and the PER. C6 cell line developed around 1996 from HER199 cell line derived from retinal cells of a human embryo. These first two cell lines were or are used for the production of vaccines against adenoviruses (no longer in production), rubella (rubella), chickenpox and shingles (herpes zoster), ebola, polio, and rabies (rabies); the second two for production or post-production control of vaccines against SARS-CoV-2 virus ("Coronavirus"). In the Netherlands, the polio vaccine is not produced on a human-derived cell line, but on a cell line derived from African grivet monkeys. CureVac's mRNA vaccine against SARS-CoV-2, whose development was discontinued in early October 2021, used HeLa cells (cervical cancer cells obtained without the knowledge of Henrietta Lacks, who died of her disease in 1951) for control testing.

During the COVID-19 pandemic in 2020, it became clear that, in addition to the classical vaccines described above (inactivated, attenuated or fragmented viruses, cultured specifically for this purpose), other types of vaccine development techniques had been prepared and are being used in the development of a vaccine against the SARS-CoV-2 virus. These are vaccines based on either laboratory-prepared surface molecules of a virus, messenger RNA (mRNA) or a vector (DNA). The mRNA and vector vaccines encode for viral surface molecules that can cause the human body to produce these molecules. The European Union took options on about eight vaccines in 2020-2021. Development of the Curevac vaccine was discontinued in October 2021. The Valneva vaccine, the assessment of which started in December 2021, like the Chinese Sinovac vaccine (which is not available in Europe), resembles a classical vaccine: they contain inactivated virus grown on Vero cells (cells obtained from the kidneys of grivet monkeys). Sanofi and Novavax's vaccines contain a molecule found on the surface of the SARS-CoV-2 virus and produced in a Baculovirus system, a production system that uses viruses found in insects. It is expected to produce an immune system response similar to that of conventional vaccines. The four other vaccines use the newer technique in which the vaccine contains mRNA or a DNA vector. The vector is an attenuated adenovirus derived from monkeys that helps to get the DNA encoding a surface protein of the virus into the cell. For these four vaccines, either HEK293 or PER.C6 cells are used in control (mRNA vaccines) or production (DNA vector vaccines).

In some documents of the Roman Magisterium rejects the use of cells from aborted foetuses. At the same time, the Congregation for the Doctrine of the Faith points out in its aforementioned instruction that there are different degrees of responsibility regarding cooperation in obtaining cell lines in a morally impermissible manner: the person who performed the abortion in the previous century and harvested the foetal tissue was directly involved in the abortion, while the person who now uses the vaccine grown on perfused cells from over 25-50 years ago no longer has any direct involvement with this abortion. There is, therefore, an indirect and distant form of cooperation in the abortion in this case. Moreover, if the user of the vaccine does not consent to abortion provocatus, it is a material form of cooperation in the abortion that took place in the distant past (cf. Chapter I.2.2.6.3). Serious reasons may justify the use of such vaccines. This is particularly the case in situations where there is a serious disease and no other vaccine or treatment is available for it. However, at least the people working with these types of vaccines, but possibly others as well, have a duty to protest to the extent possible against the unauthorised way in which the cell lines were obtained and to encourage the search for other production options. Regarding the SARS-CoV-2 vaccines, the Congregation for the Doctrine of the Faith reiterated this position (grave situation, removed, no direct involvement in the abortion at the time, duty to press for other production methods). Obviously, prudence here requires a different action from doctors or nurses, than from parents who have their child vaccinated.

The use of DNA, RNA and vector vaccines involves administering DNA or RNA that is incorporated directly or with the help of the vector into certain cells in the body with the aim that these cells, e.g. antigen-presenting cells, start producing viral surface molecules against which the immune system can then start a defence

response. Intentionally making the body produce these molecules in this way does not encounter a moral dilemma. It is a safe way of exploiting natural properties of the immune system. With the vaccine, it leads the human cell to produce one or a few viral surface molecules; with a viral infection, the cell starts making many full copies of virus. The administered mRNA enters only the cytoplasm (cell body), and not the cell nucleus, of certain body cells and leads there to production of surface molecules (peptides or proteins) that will be presented by the cell on its surface. When DNA vaccines or vector vaccines are used, DNA does travel to the cell nucleus in certain body cells. Even then, the situation resembles an ordinary virus infection. The vectors used so far are derived from monkey viruses and cannot replicate themselves in humans. So on theoretical grounds, there is no risk that these vectors could have harmful effects in humans.

According to some, introducing mRNA or DNA into the body would be a form of genetic engineering. This is incorrect: the mRNA most likely does not alter the human's own DNA. The vaccine DNA could, however, change human DNA in some cells, but it is important to understand this well. Viruses themselves can also change human DNA during infection. Some changes are even still inherited in the DNA. However, this is different from what is meant by genetic engineering. In the latter case, the act aims to change the DNA and then also with the aim of editing better properties of the organism. In the case of vaccination, it is about curing a disease and the change in DNA is not intended at all. This makes it not comparable to genetic engineering.

1.5.2.4 What to do if someone refuses the vaccination of themselves or their children?

In the context of the necessary 'informed consent', it is to be welcomed that people form their own thoughts about the medical interventions and applications a person undergoes, including with regard to vaccination. However, if the consequence of this is that vaccination rates fall, one has to wonder whether these choices are right. Where people can and may still weigh up for themselves whether they consider the risks proportionate, additional considerations apply in terms of the health of society as such. Vaccination is a particularly light intervention that eliminates serious diseases. This trade-off should always be in favour of vaccination. Moreover, people who do not get vaccinated on the basis of loss of sense of urgency will begin to see the need for it again when it becomes clear that some infectious diseases are gaining ground again.

A difficult question is what should be done in respect of someone who refuses vaccination of himself or his children. According to the principle of freedom and responsibility (see Chapter I.2.2.4), a person cannot in principle be forced to undergo treatment. This also applies to vaccination. At most, the competent government may decide to make people undergo treatment under duress for the sake of public welfare. For instance, under certain circumstances, it may order that a prisoner on hunger strike be forcibly administered food and fluids to prevent him from becoming a martyr in the eyes of his supporters. Forced vaccination of people who have conscientious objections to it convinced in conscience that they should not have them vaccinated, however, goes too far. The same applies with regard to the temporary disqualification of parents from parental rights to vaccinate their children. Forced vaccination would be a traumatic experience for the people in question and for the parents and their children. It should be borne in mind that a vaccination rate of 95% and above provides society with adequate protection against epidemics of serious infectious diseases. From this perspective, it is acceptable if a small percentage of people are not vaccinated on the basis of conscientious objections.

The government can take a number of measures to try to increase vaccination coverage. Broadly speaking, there are two types of measures, suggested by the media and politicians and applied to varying degrees in

western countries (France, Germany, Britain, Australia). The first measure involves a financial incentive, mainly in the form of a child benefit reduction for parents who do not have their children vaccinated; the second measure involves banning unvaccinated children from childcare. This is also already practised in the Netherlands, although it is not yet allowed under Dutch law. Incidentally, childcare managers are already finding so much sympathy for their position even now, especially because of the risks that children younger than the vaccination age face when unvaccinated children are admitted to the nursery, that it is expected that there will be no point for parents to take legal action against this decision. However, if these measures become legally enshrined, this will also meet resistance. Support for the desire to forgo vaccination should not be underestimated. That this support is strong is evidenced by the falling vaccination rate

Is it right to punish people who reject vaccination financially or practically for it? Society has many proper examples of punitive measures for undesirable behaviour, ranging from a visit by the school attendance officer to parents of truant children (behaviour that does not comply with the regulations on compulsory education), to excise taxes on alcohol and tobacco, to encourage people to live a healthier way of life (while the use of alcohol and tobacco is not prohibited by law). The question here is whether behaviour is harmful and needs correction. That maintaining high vaccination rates is important for society needs no argument. In this sense, the government may certainly take guiding measures in view of the common good, for which it bears primary responsibility. The severity of the measures to be taken against undesirable behaviour should be in proportion to the seriousness of the damage that that undesirable behaviour causes to the public welfare. Clearly, a high vaccination rate is important, but also that if a small percentage of the population rejects vaccination, it does not pose a high risk of spreading infectious diseases and thus does not have a serious impact on public welfare. Moderation in the application of punitive measures therefore seems appropriate. The government should therefore first try to achieve the desired vaccination rate among the population through information and media campaigns before considering punitive measures. This involves providing accurate and reliable information about the risks of not vaccinating for those involved and society and about the risks associated with vaccination. It will have to be made clear that fully proportionate to the risks of the infectious disease it prevents. It will also be necessary to point out the responsibility one bears not only for one’s own health but also for that of society.

There is thus a delicate balance: vaccination is morally right and also a moral duty and should be promoted. However, there are also good reasons not to judge harshly people who want to refrain from vaccination, especially when they are convinced that it goes against their conscience. Vaccination implies an act, which, more than any other, presupposes the free consent of human beings: it involves an intervention in the body. Admittedly a limited one, but the intrusion and intervention into the human body in any form is a delicate subject. In the Dutch Constitution, this sensitivity is expressed in Article 11:

“Everyone has the right, subject to any limitations to be imposed by or under the law, to the inviolability of his body”. Compared to other (international) treaties or the Universal Declaration of Human Rights, this right to the integrity of the body is very explicitly articulated in the Dutch Constitution.

1.5.2.5 Vaccination in situations of risky behaviour

A relatively new vaccination is vaccination against Human Papillomavirus (HPV), which has been part of the National Vaccination Programme in the Netherlands since 2009. Several variants of HPV exist: types 16 and 18 are the most common and dangerous viruses. They can cause cervical cancer in women. The HPV vaccine currently offered to girls in the Netherlands in the year of their 13th birthday therefore protects against these

types 16 and 18.

An interesting issue is how natural it is to take advantage of this HPV vaccination. The risk of HPV infection occurs in people who are sexually active with alternating partners. The increase in cervical cancer in the population in the last 40 years is therefore attributed to the changed, “freer” sexual behaviour during this period. Infection with HPV is in principle avoidable through a monogamous lifestyle. A similar moral dilemma arises with the increasingly common PrEP use, especially among gay people. While this medication reduces the risk of HIV infection, at the same time it almost always aims to allow unlimited sexual intercourse with a reduced risk of HIV transmission. This, however, is a reprehensible intention. The objective of prophylactic acts is not to make immoral acts less risky and thereby facilitate them.

Decisive in ethical terms is the purpose with which vaccination takes place. If it is to protect against diseases to which one does not expose oneself through freely chosen behaviour, then vaccination is a good thing. This applies, for example, to a man who has led a promiscuous life for some time, but later makes the conscious choice of a monogamous marriage. A woman can protect herself against AIDS through vaccination when her husband may be a carrier of HIV. Similarly, medics at increased risk of HIV infection can take advantage of a prophylactic medication directed against it.

1.5.2.6 Conclusion

Vaccination is a sensitive subject because it concerns personal freedom, the integrity of one’s own body, one’s own health, but also the health of other people and of society as such. All these aspects deserve attention. However, the starting point is that in general it is morally justified, good, necessary and also morally obligatory to use vaccines, with the aim, on the one hand, of protecting the vaccinated person from contracting possible contagious diseases and, on the other hand, of taking responsibility for fellow human beings, who have a higher chance of contracting a contagious disease if fewer people get vaccinated . However, it is going too far denying someone the freedom to reject vaccination, especially if he is convinced in conscience that he should not have himself or his children vaccinated. At the same time, every effort should be made, through good and objective information, to persuade people to freely choose vaccination.

1.5.3 Prenatal diagnostics and preventive medicine

In both public, official and scientific parlance, prenatal diagnostics is also often referred to as preventive diagnostics. The ethical aspects of this have been dealt with in Chapter II.4.2.1. However, there is much to be said against this. In general, prenatal diagnostics does not concern the prevention of diseases that may occur later, but the early detection of abnormalities that are already there, but without the application of prenatal diagnostics would only manifest themselves at or after birth. It is, therefore, incorrect to classify prenatal diagnostics under preventive medicine. Prenatal diagnostics may in some cases be useful for intrauterine surgical intervention even before birth to prevent the serious consequences of certain conditions and also to be able to take the required measures immediately after birth. Prenatal diagnosis, however, generally does not involve treatment of the abnormality or condition found, but rather proceeds to abortion provocatus, an intrinsically evil act, when the unborn child is diagnosed with an abnormality (see Chapter II,4).

IV. Medical Care for Life: Therapeutic Intervention

F.J. van Ittersum – W.J. Eijk

1. Diagnostics, prevention, therapy and rehabilitation – *J.A. Raymakers en F.J. van Ittersum*
2. Clinical research – *J.A. Raymakers*
3. Organ donation and transplantation – *F.J. van Ittersum and W.J. Eijk*
4. Somatic gene therapy – *W.J. Eijk*
5. Psychiatry – *F.L.E. de Wever and F. Hamburg*
6. Addiction – *F.L.E. de Wever and F. Hamburg*

Links of the chapters available on this website are visible in the menu at the left side.

Authors

F.J. van Ittersum – W.J. Eijk

Information on authors of chapters available online

His Eminence Willem Jacobus Cardinal Eijk, MD PhD, STL, is Archbishop of Utrecht. He completed his medical studies with a MD. Degree in 1978. After his medical training, he began his specialization training in internal medicine, but, before completing his specialization, he switched to philosophical and theological studies, and was ordained a priest in 1985. He obtained a Ph.D. Degree with a dissertation on euthanasia from Leiden University in 1987. He obtained a second Doctorate from Saint Thomas Pontifical University in Rome, with a dissertation on genetic manipulation. He was created cardinal in 2012. He is a member of the Pontifical Academy for Life and President of the Foundation for Medical Ethics (The Netherlands).

The Reverend L.M.J Hendriks PhD, STD., is professor of philosophical ethics and moral theology and Vice Rector at the Major Seminary Rolduc in Kerkrade, the Netherlands. He was ordained a priest in 2002, and obtained a Doctorate from the John Paul II Institute for Marriage and the Family in Rome, with a dissertation on the structure of human action according to Thomas Aquinas.

J.A. Raymakers, MD., PhD., is a medical doctor. He is a retired specialist in internal medicine, who worked at University Medical Centre in Utrecht. From 2005 till 2019, he was the Secretary of the Foundation for Medical Ethics. He was a corresponding member of the Pontifical academy for Life from 2011-2017.

Prof. F.J. van Ittersum, MD., PhD., MSc, is a medical doctor, specialist in internal medicine an nephrology, epidemiologist, professor in nephrology, who works at Amsterdam UMC, Amsterdam. He is a member of the Board of the Foundation for Medical Ethics and has been a corresponding member of the Pontifical Academy for Life since 2011. He is has been chairing the Dutch Network of Catholic Health Care Professionals since 2017 and has been the Secretary-General of the European Federation of the Catholic Medical Associations since 2021.

Preface to on-line texts (as of 2023)

F.J. van Ittersum – W.J. Eijk

After the introduction of the first edition in 2014, the Manual of Catholic Medical Ethics has found its way to many interested parties: medics, moral theologians, priest students and other students, among others. It is in use as a study book and reference work. The printed version from 2014 is still remarkably up-to-date. In a span of 9-10 years, there have been some developments in biology and medicine that are not discussed in the book. As these can be overlooked for the time being, these new developments are published on this website as supplements to the Manual of Catholic Medical Ethics (2014 version) edited by W.J. cardinal Eijk, MD PhD STL L.J.M. Hendriks, PhD, STD, and Prof F.J. van Ittersum, MD PhD MSc. These additional texts will be provided with a publication date.

The editors

February, 2023

Preface to the English Edition (2014)

Contemporary popular opinion, influenced by the expressed opinions of many leading members of the Enlightenment, would have us believe, unfairly, that religion was an obstacle to the project of modern science, and that the mediaeval period was a particularly egregious example of religion's hostility to science. In fact the connections between the practice of medicine, natural philosophy, and the JudeoChristian Tradition are of longstanding. From the early Hebrew laws on what food could not be eaten (a primary healthcare requirement), to the strong promotion of the Hippocratic Oath by early Christians, the provision of hospices for the sick and dying from the 11th century, and onwards into the contemporary age, the Christian religion and provision of healthcare have been inextricably intertwined.

Perhaps the fairest description of the relationship between Christianity and natural philosophy in the Middle Ages was one of "creative tension" (James Hannan, *God's Philosophers*. Icon Books, 2009). While there certainly were some restricting rules applied by the Church where the pursuit of the natural sciences was concerned, the fact is that there were very significant advances in science and technology in the mediaeval period thanks in large part to the scholars active in the religious tertiary foundations of the time. These advances provided the platform for major developments from the 17th century onwards.

From about the middle of the 19th century, mankind has witnessed a revolution in the development of medical science and with it the practice of medicine. The Catholic Church contributed greatly to this revolution in its ongoing provision of hospitals, medical schools and research facilities. The Catholic Church's engagement with medical science and medical care has always been based upon her conviction that truth is indivisible, that there can be no opposition between the truths of revealed religion and the truths discovered in the sciences, and that Christians are committed to the care of the sick and dying (cf Matthew 25:36).

But today, in an increasingly secularist environment, the contribution of the Catholic Church to ethical reflection on medical and scientific developments is often marginalised as having no place in the public square because it is based upon "religion", and therefore not open to reason.

This *Manual of Catholic Medical Ethics* is a timely reminder of the reasonableness of the Catholic moral tradition,

of its openness to the truth where the scientific facts of the matter are concerned, and of its overriding concern for the good of human persons living in a human community.

In English-speaking countries public debate on medical-ethical issues is often characterised by the underlying assumption that facts can be reported and interpreted as facts in a completely objective way, unhindered by the prejudices of the religious mind. But as Bishop Anthony Fisher has reminded us (Fisher 1991, 204): "The simplistic dichotomy between fact and interpretation, objectivity and subjectivity, is illusory." Bishop Fisher cites, with approval, the moral philosopher Alasdair MacIntyre (1985, 79):

> *'Fact' is in modern culture a folk-concept with an aristocratic ancestry. When Lord Chancellor Bacon as part of the propaganda for his astonishing and idiosyncratic amalgam of past Platonism and future empiricism enjoined his followers to abjure speculation and collect facts, he was immediately understood by such as John Aubrey to have identified facts as collectors' items, to be gathered in with the same kind of enthusiasm that at other times has informed the collection of Spode china or the numbers of railway engines. The other early members of the Royal Society recognized very clearly that, whatever Aubrey was doing, it was not natural science as the rest of them understood it; but they did not recognize that on the whole it was he rather than they who was being faithful to the letter of Bacon's inductivism.*
>
> *Aubrey's error was of course not only to suppose that the natural scientist is a kind of magpie; it was also to suppose that the observer can confront a fact face-to-face without any theoretical interpretation interposing itself. [Emphasis added]*

Bishop Fisher adds (1991, 203-204):

> *Among important critics of the assumptions operative in the sciences have been Polanyi, Kuhn, Lakatos, Hanson and Feyerabend. They have exposed some of the assumptions behind naive inductivism and the positivist distinctions between fact and interpretation, neutral objective science and committed subjective metaphysics and religion.*

The reality is that facts and the use of facts are always received by human persons and interpreted through the prism of whatever philosophical framework a person may bring to bear on the subject, including of course philosophical assumptions of which the person may himself be unaware and which remain undeclared. Bioethics scholars generally, though, do declare their adherence to one or other competing moral philosophies so that their conclusions may be evaluated in terms of those philosophical positions.

In this Manual, the authors not only clearly articulate the theological and philosophical position which is adopted throughout the book, they also examine and defend this approach in dialectical relationship with other philosophical ways of doing ethics. Scholars and students who want to understand better the foundations of the Catholic Church's fundamental moral position will be greatly rewarded by the contributions of Cardinal W.J. Eijk in his Introduction to the book as a whole, and also in Chapter 1 which follows. Cardinal Eijk brings to bear on the subject material his medical qualifications (gained before he entered the priesthood) and his doctoral qualification in philosophy and theology.

The scope of medical ethical issues covered in this Manual is breathtaking with the eight contributors representing a very wide range of professional expertise. The detailed scientific material presented is impressive in its range and depth and provides a sound basis for ethical reflection.

This English edition of the *Manual of Catholic Medical Ethics* reveals the high level of sophistication of bioethical reflection in the Netherlands. The authors understand that bioethics debates take place at both the local and international levels, and rightly underscore the vital importance of the Catholic contribution to those debates.

This is an important book for all nations. That it is now available in English should secure it a place in faculties and universities across the globe, and a place in the libraries of all who want to understand better the crucial intellectual and cultural contribution of the Catholic Church to bioethics.

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Preface

In 2008, the Board of Directors of the Foundation for Medical Ethics (Stichting Medische Ethiek, www.medische-ethiek.nl) in the Netherlands issued a manual of Catholic medical ethics entitled, *Handboek Katholieke Medische Ethiek,* published by the Publishing Company Parthenon in December 2010.

Since a work in the Dutch language is only accessible to a rather limited public, it was subsequently decided to adapt the manual for use by English-speaking readers. The present edition of the *Manual of Catholic Medical Ethics* is the result.

The term “Catholic” in the title is significant, because it is the intent of the present book to present the Catholic teaching on medical ethical issues in an unabridged, clear, and, above all, also a wellargued manner.

Members of the Board of Directors of the Foundation of Medical Ethics and others contributed to the present *Manual*, which took form under the leadership of His Eminence Cardinal Willem J. Eijk, M.D., Ph.D., S.T.L., Archbishop of Utrecht, the Netherlands.

For the translation into English, the authors are indebted to Sister M. Regina van den Berg, F.S.G.M., and to Dr. Janthony Raymakers who put much effort into the translation and adaptation of the Dutch text. Moreover the authors want to express their gratitude for the important contribution of Fr. Dr. John I. Fleming, who carefully read the entire manuscript and offered a great number of useful suggestions for correction and adaptation to an English-speaking readership.

In the arrangement of the book, much attention is given to the explanation of the general principles of medical ethics, based on a Catholic view of man. In line with Catholic tradition, philosophical as well as theological argumentation is used throughout. With regard to philosophical argumentation, Thomistic philosophy is taken as point of departure. These explanations are then followed by a discussion of different issues, which are arranged according to the phases of human life in which they occur: developing life, transmission of life, therapeutic and non-therapeutic care, and care for the dying. The book concludes with a discussion of some social aspects of health care and a new translation of the Hippocratic Oath with a commentary. Throughout the book, an effort has been made to include contemporary developments in health care. An ample bibliography makes available all the sources, and an elaborate index allows for use of the book as a reference.

We hope that this book may be of help to medical professionals and other professionals in healthcare, to pastoral care workers, and to those who simply interested in understanding the difficult issues we encounter nowadays in the field of clinical medicine and in biomedical research. At the same time, we hope that the readers will be inspired by the Catholic vision of health care, which finds its ultimate example in the person of Jesus Christ and in His loving care for every human being without limit or boundary.

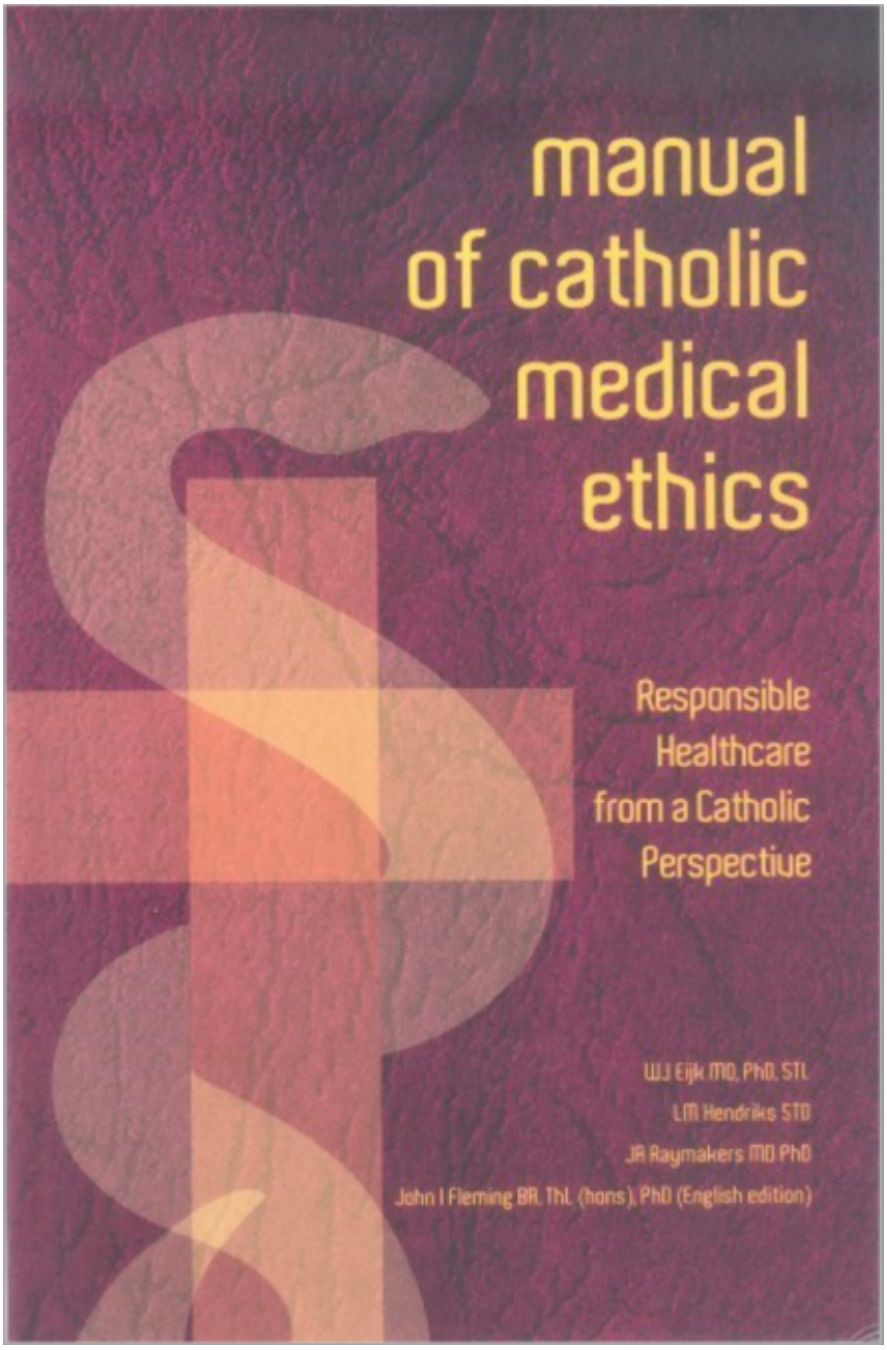
We hope that this book will of use to many readers.

The Editors
Spring 2014

MCME revised texts as of 2023

F.J. van Ittersum – W.J. Eijk

This section of the website publishes the revised texts of the Manual of Catholic Medical Ethics as of 2023. As soon as revisions of texts are completed, they are published, with a publication date which then indicates the version. The menu in the left-hand sidebar shows which texts have been revised and are available.


manual
of catholic
medical
ethics
Responsible
Healthcare
from a Catholic
Perspectiue
W.J Eijk MD, PhD, STL
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JA Raymakers MD PhD
John I Fleming BA, ThL (hons), PhD (English edition)