

# Should patients who use illicit drugs be offered a second heart-valve replacement?

**SUMMARY** Intravenous drug users (IVDUs) have an elevated risk of contracting infectious endocarditis. Most of them have good effect from medical treatment, but some will need valve replacement. Until a few years ago, our hospital withheld valve surgery if patients with intravenous drug dependency and infectious endocarditis came to need a second valve replacement. However, there are no consensus guidelines for treatment of this group of patients, and a dearth of data on the effects and benefits of interventions. Using a method of ethical analysis, we here discuss whether it is appropriate to offer valve surgery to drug users for a second time.

IVDUs are particularly prone to infectious endocarditis, with a lifetime incidence of 1–11% (1, 2). Among the estimated 8 200 to 11 500 IVDUs living in Norway (3), there are indications of an increasing incidence of endocarditis with damage to the valves, as in other Western countries (4). At Haukeland University Hospital, this group of patients account for an estimated 10–15% of the approximately 50 annual cases of infectious endocarditis. Most patients are treated conservatively with antibiotics, but some will need surgery involving removal of the infected valve and implantation of an artificial heart valve. The patients tend to be relatively young and seriously ill, and heart surgery can constitute life-saving treatment in the short term.

There is a high risk, however, that the patients will resume their intravenous drug abuse after having gone through endocarditis (4). They will thus have an elevated risk of a new infection and destruction of the implanted heart valve (5). There may be clear indications for an operation, but the benefits of the intervention and the defensibility of the costs involved may be questioned (6). In this article we discuss whether offering a second round of valve replacement surgery to illicit drug users is appropriate.

## Method of analysis

We have used a model for impartial ethical analysis based on a method of ethical case analysis, developed by Kymlicka (7), modified by two of the co-authors (8). This modified model, which consists of seven steps to identify key ethical factors in dilemmas (BOX 1), is used in the present study. A similar method is used by many of the Norwegian clinical ethics committees (9).

The advantage of the model is its ability to elicit assessments of available evidence and clarify the decision as seen from the perspective of all parties concerned, as well as identify any possible conflicts between ethical principles. This enhances the impartiality of the analysis. The authors have met on

numerous occasions, and have debated the knowledge base and the interpretation of the principle of equal treatment in particular.

## A seven-step ethical analysis

### Step 1. What is the ethical dilemma?

Is it appropriate to offer repeat valve replacement surgery to intravenous drug users with infectious endocarditis?

### Step 2. What knowledge is available regarding the outcome of the various alternatives?

In the following we summarise the available knowledge on which we have founded our analysis, for assessment of the prognosis with and without repeated valve replacement surgery. We related our search to the four priority criteria that are applicable in Norway (BOX 2) (10).

*Prognosis.* Studies from different countries and different populations of IVDUs show that they have low quality of life, a risk of death which is 6–54 times higher than the normal population and that infectious endocarditis is the cause of approximately 5–10% of this mortality (11, 12). We found no high quality studies showing the prognosis for patients with an intravenous drug dependency who need a new valve, but fail to undergo surgery. It is known, however, that the prognosis for endocarditis is worsened by cardiac failure, infection with *Staphylococcus aureus* and on whether the infection is deeply situated, with periannular complications (13–15). If all these three factors are present, the risk of death is 80% (13, 14), and there is hence indication for surgery.

In a retrospective study of 4 106 patients admitted to an intensive care unit, infectious endocarditis was detected in 33 patients (0.8%) (16). In those who underwent surgery mortality amounted to 35% compared to 84% in those who only received medical treatment. Due to the unavailability of accurate data, in our further ethical analysis we have therefore assumed that patients with

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## MAIN MESSAGE

Until a few years ago, intravenous drug users were not offered a second heart-valve replacement for infective endocarditis.

Based on the principle of equal treatment and expected survival, we claim that this group of patients should receive the same treatment as other patients in whom a corresponding treatment effect is expected.

Among the authors, the majority were of the opinion that this group should be offered surgery irrespective of whether the substance addiction was likely to persist after the surgery or not.

The minority were of the opinion that the patient's ability to cope with addiction should be assessed on an individual basis before surgery is offered.

**BOX 1**

**A seven-step model for impartial analysis and identification of key ethical factors in dilemmas. The model is based on a method for ethical case analysis developed by Kymlicka (7). It has been modified by two of the authors, and encompasses seven key questions.**

Key questions for impartial analysis

Step 1. What is the ethical dilemma?

Step 2. What is the available knowledge regarding the outcome of the various alternatives?

Step 3. Are the decisions regulated by any laws, regulations or guidelines?

Step 4. Who are the parties involved?

Step 5. What are the potential burdens and benefits for the parties involved?

Step 6. Whose interests are in conflict?

Step 7. Which principles and values are in conflict?

intravenous drug dependency, infectious endocarditis and a need for repeat valve surgery have less than a 20 % chance of survival without surgery.

*The effect of surgery in cases of infectious endocarditis.* There are no randomised studies that show long-term outcomes for IVDU patients who have undergone surgery (17). It is uncertain whether there are any significant differences in short-term and long-term survival between intravenous drug users and other patients who undergo first-time surgery for infectious endocarditis (5, 18–20). One study estimated the ten-year and fifteen-year survival rate to 66 % and 54 % for older, non-addicted patients and to 56 % and 42 % for younger IVDUs (18). For the entire population of endocarditis patients needing surgery, mortality increases somewhat after a repeated operation, but some studies nevertheless report a five-year survival rate of 40–86 % (21).

At Haukeland University Hospital, a limited number of patients with an intravenous drug addiction have undergone a second surgery during the last five years. On the basis of our experience with this group of patients and the available literature, we estimate survival of at least 1–2 years among those who maintain their drug habit after their first surgery. In our further analysis we will use this as our basis.

*Resource use.* We estimate that a patient with infectious endocarditis will need at least six weeks of hospitalisation. The total expenses for such hospitalisation may amount to NOK 1 million (USD 170 000). Whether this treatment should be considered cost-efficient depends on the number of

quality-adjusted years of life over which the costs should be distributed and the cost of additional treatment, but there are no specific studies or estimates available with regard to this particular group of patients.

*Step 3. Are the decisions regulated by any laws, regulations or guidelines?*

*Local professional guidelines.* The Department of Thoracic Medicine, Haukeland University Hospital, follows the practice of offering elective open heart surgery to patients who need valve replacement and have a life expectancy of more than two years.

*National guidelines.* There are no specific guidelines for surgery, but Norwegian practices for treatment of infectious endocarditis broadly adhere to European guidelines (13).

*International guidelines.* The most recent guidelines from the European Society of Cardiology recommend the same indication for surgery in case of infectious endocarditis in intravenous drug users as in others. At the same time, they recommend a generally more conservative approach, because of the far higher risk of recurrent infections if the drug addiction persists (13). The guidelines provide no further reasons for this recommendation. The guidelines from the Society of Thoracic Surgery and the Infectious Diseases Society of America do not specify any treatment for this group (22, 23).

*Legislative acts.* Legal issues revolve around the assessment of the entitlement to necessary or prioritised health care. Such an entitlement presupposes that the criteria for setting of priorities have been fulfilled (10).

*Step 4. Who are the parties involved?*

The parties involved include the patient, fellow patients, next of kin, health personnel, other groups of patients, the health enterprise in general and the service provision to drug users in particular, municipal care services for drug users, and society.

*Step 5. What are the potential benefits and burdens for the parties involved?*

*The patient.* It will be an advantage to the patient to receive surgical treatment with an expected benefit of more than 1–2 years of life. Correspondingly, not receiving such treatment will be a disadvantage.

*Fellow patients.* Treatment of this group of patients may help produce expertise that can be beneficial to other patients. On the other hand, unruly and difficult patients with a drug dependency can be distressing for their fellow patients.

*Next of kin.* Most next of kin will perceive provision of potentially life-saving cardiac surgery to this patient group as an advantage, despite the fact that the patient's drug addiction may be a strain on many of them.

*Health personnel.* To these, saving a life will be seen as an advantage, and they will also accumulate more experience and com-

petence. It could be a disadvantage, however, that the treatment may include having to deal with behavioural problems, threats or even episodes of violent behaviour.

*Other groups of patients.* All patients who need valve replacement surgery will occupy beds in the emergency ward, affect the surgical capacity and spend long periods in hospital. Since health budgets are limited, prioritising one patient group may cause delays or provision of less than optimal services to other groups.

*The health enterprise.* The health enterprise is committed to providing adequate care to the patients in their catchment area. It has been decided to give priority to services for drug users, but these concerns must be balanced against the consequences this will entail for other patients.

*Municipal health services.* The municipal health services should follow up the patients after surgery, but in most cases their resources are insufficient. Uncooperative drug users may represent a greater than normal care burden for the staff.

*Society.* Society may document its ability and willingness to prioritise a disadvantaged group of patients, but nevertheless risk using resources inappropriately. Norwegian authorities have not specified a threshold value for this, as has been attempted in the UK (24). However, in its processing of several cases, the National Council for Priority Setting in Health Care has suggested a limit to resource use of NOK 300 000–800 000 (USD 51 000–136 000) per quality-adjusted year of life (25).

*Step 6. Whose interests are in conflict?*

The wish of the patient and next of kin that the patient should receive life-saving treatment may conflict with the needs of other groups of patients and society's limited resources. The health personnel are faced with patient in need of emergency care, while at the same time they should fulfil the role of gate-keepers with regard to the use of shared resources. In the municipal health services, similar conflicts may occur between the needs for scarce resources in various groups of patients.

*Step 7. Which principles and values are in conflict?*

*The principles of doing good and causing no harm.* An emphasis on the principle of doing good would point in favour of surgery, since surgery will be a considerable advantage to many in this group. An emphasis on the principle of doing no harm will point in the same direction, since the risk of harm by not operating (the patient will most likely die) tends to be greater than the risk of harm inflicted by operating.

*The patient's preferences (autonomy).* On the basis of our clinical experience, we assume that most informed patients would want this treatment.

**BOX 2****Criteria for the right to necessary health assistance from the specialist health services, taken from the Regulations on Priorities in the Health Services (10)**

The patient will have a certain loss of prognosis with regard to life expectancy or a not inconsequential reduction in quality of life if health assistance is delayed.

The patient can be expected to benefit from the health intervention.

The expected costs are reasonable when seen in relation to the effects of the intervention.

In addition, satisfactory documentation is required for all three items.

*The principle of equal treatment.* It is generally accepted that everybody should be treated equally. If priorities have to be made, the prioritisation requirements shall be followed (BOX 2) (10). How the criteria should be balanced against each other, however, is not specified; this requires discretionary judgement and open procedures (26).

On the basis of severity criteria, these patients should be given priority, since most of them will die without treatment. On the basis of expected benefit criteria, they should also be given priority, since we assume that a second valve replacement may provide them with an additional life expectancy of 1–2 years. Long-term survival depends on whether the patient stops abusing substances, and we assume that young people who succeed in ceasing their drug use will survive for far longer than 1–2 years (27). We find it difficult to provide a clear answer to the question of whether there is a reasonable balance between the costs and the benefits. It is difficult to comply with the documentation criterion for both expected benefit and cost-effectiveness.

*The principle of responsibility for one's own health.* A criterion for setting priorities which is frequently discussed, but not formalised, concerns the emphasis to be placed on the patient's responsibility for his/her own health (28). The Lønning Commission (1987) stated that patients should not be deprived of treatment opportunities solely on the basis of their former lifestyle. Future lifestyle, on the other hand, may be included in the assessment of a treatment sequence (29). COPD patients who will benefit from continuous oxygen treatment at home must have been smoke-free for three months before they can receive home treatment, and must stay smoke-free to retain this option. Patients with alcohol-induced liver cirrhosis must have been

alcohol-free for six months and have a good social network to be granted a liver transplantation. However, these examples are different in several respects. Patients with endocarditis most often have an acute need for a new valve, and the treatment cannot be delayed until the patient has gone through a substance-free period. Like in the case of liver failure caused by alcohol abuse, the need for treatment may be acute, but in contrast to organs, artificial valves are not in short supply.

**Result of the analysis**

With the aid of the ethical analysis model we have discussed whether patients who are intravenous drug users should be offered a second valve replacement surgery when suffering from infectious endocarditis. Three conclusions are relevant:

- The patient is not offered a second valve replacement.
- An individual assessment is made to determine the patient's opportunities to benefit from a second valve.
- All patients are offered a second valve replacement as a main rule.

Until approximately five years ago, the first of these alternatives was the prevailing practice in our hospital. Based on a discussion of the principles of doing good and of doing no harm, the majority of the authors endorsed the third alternative, claiming that as a main rule, a second valve replacement should be offered to IVDUs in case of recurrent infectious endocarditis. A minority of the authors supported alternative two.

Even though the knowledge base is weak with regard to effects, we believe that there is reason to expect survival for 1–2 years. This is as good as for comparable groups that are given priority. In comparison, advanced and expensive chemotherapy is administered to cancer patients who are expected to survive for only a few months (30, 31). If a careful individual assessment seems to indicate that special contraindications are present, for example conditions indicating that the treatment will provide very little expected benefit, the authors find it acceptable to refrain from surgical treatment. We find it ethically unacceptable to refrain from life-saving treatment if this is done on the assumption of insufficient follow-up by the primary health services.

The authors are divided in their views of the importance to be placed on the patient's responsibility for his/her own health and ability to cease their injection practice, and how these concerns should be weighted when a second valve replacement surgery is considered. A minority claimed that the patients' opportunity and commitment to cease their use of intravenous drugs needed to be emphasised in the assessment of whether a second valve replacement surgery should be offered. The majority

claimed that requiring substance abusers to succeed in ceasing their abuse in order to receive potentially life-saving health assistance, without any guarantees of optimal follow-up after discharge, is unreasonable. The majority regarded it as especially unreasonable that the principle of responsibility for one's own health should predominate, since substance dependency can be regarded as a disease with multiple causes and with possible failure on the part of health or social services ever since the patient's childhood years.

**Conclusion**

We believe that prioritisation of patient groups that should receive active treatment ought to be made at a general level, and not left to the individual clinician. If national guidelines for this clinical decision are to be established, a reliable level of evidence and a wider systematic consultation with the stakeholders involved are required. Some of the authors have initiated Nordic collaboration to produce better data on the costs and benefits of repeated valve replacement surgery in this group of patients.

Treatment practices for substance abusers who need a second valve are evolving – surgery is now performed in some cases, whereas previously this happened rarely or never. We asked ourselves whether this should be given priority. By using a model for systematic analysis, we have attempted to make explicit many of those considerations with which decision-makers are confronted when they are facing such clinical choices. The discussion illustrates not only the importance of solid documentation for making a well-considered choice, but also the necessity of clarifying the values and principles that have an impact on our priorities. We hope that our work can inspire others to initiate similar dialogues on ethics, across professional boundaries.

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