Tetanus vaccination tends to be the last hold-out for those questioning vaccination. It certainly was for Dr Gaublomme. Challenged to look again at the facts associated with both the disease of tetanus and the vaccine meant to prevent it, his exhaustive research led him to conclude that the vaccine may not work as well as promised and indeed could be more dangerous than we have been told.

The disease

Tetanus as a clinical entity is linked to a bacterium, *Clostridium tetani*. Obviously, the germ is not as malicious as one may think because it lives quite harmlessly in the animal and human intestinal tract[1]. It is not the very presence of the bacteria which causes the trouble, but the toxins that are produced by the bacteria under anaerobic conditions, that is, where the bacteria operates in an environment free of oxygen. These toxins can be spread through the blood vessels and finally affect the nervous system causing tetanic muscle contraction and pain. The condition is extremely painful and potentially lethal.

Tetanus morbidity is very low in industrialised countries. In the USA, for example, there are only about 50 cases a year[2]; in Germany, 17[3]. (Ed. note – there are an average of 10 cases of tetanus reported in Australia each year, almost all in women over the age of 50. There has only been one case of tetanus reported in childhood since 1963.)

Mortality figures range between 33%[4] and 20%[2]. The incidence is higher in tropical countries and under poor hygienic conditions. Mortality is 135 times higher in developing countries compared to developed countries. In those countries, tetanus in newborns plays a very important role. Most of those cases are caused by using dirty, rusty scissors when cutting the umbilical string of the newborn.

The vaccine

1. Efficacy

Prophylaxis against tetanus raises serious theoretical and, above all, practical questions, since the disease itself is known not to induce immunity. If the disease cannot induce protection, how can a vaccine? Antibody levels do not rise until 4 days after vaccination[5], so vaccination at the time of injury is of no use.

Passen writes: "There is no absolute or universal protective level of antibody... The level of neutralizing antibody in humans currently considered protective, 0.01 antitoxin unit/mL, is based on animal studies that correlated levels with symptoms or death"[5]. This figure was proposed by Sneath in 1937, and subsequently accepted by most investigators. But not everybody agreed. "Ipsen found that there is a distinct but specific relationship to toxin challenge in each species. Experimental human data are extremely limited and insufficient for analysis." Vieira et al confirm this: "This minimal protective level is an arbitrary one and is not a guarantee of security for the individual patient"[6].

The advantage of routine vaccination can be questioned based on the data given by Peebles[7]. Although the author supports a 4-dose primary vaccination schedule, the simple facts he offers should make us reflect: he bases his analysis upon the 235 cases reported in the USA in 1966. Thirty-four of these cases occurred in infancy, "and presumably most of these were neonatal and could not have been prevented by immunisation of the individual child". Peebles further calculates the annual risk of acquiring tetanus at 1 per 300,000 in unimmunised people. Crossing the street while going to work is obviously more life-threatening than that.

Cunningham, ironically, writes that "there is nothing unusual about this moderate titre, obtained approximately three months after the second of two injections of tetanus toxoid separated by six weeks"[8]. If he says so...

Edsall, in 1959, already mentioned vaccine failure[9]. During the Second World War, 5 US soldiers died from tetanus; one of them was fully immunised, the others partly. Also among the survivors of tetanus infection, 50% were fully immunised, and part of the other 50% were partly immunised[10].

During that same war, the British Army counted 22 tetanus cases, and half of them died; all of the deaths were partly immunised[10]. The drop in tetanus cases between 1950 - 1974 from 2.5 to 0.1 cases/100,000 population is not only a result of vaccination; mechanisation of farming and other changes in living habits also played a major role[10].

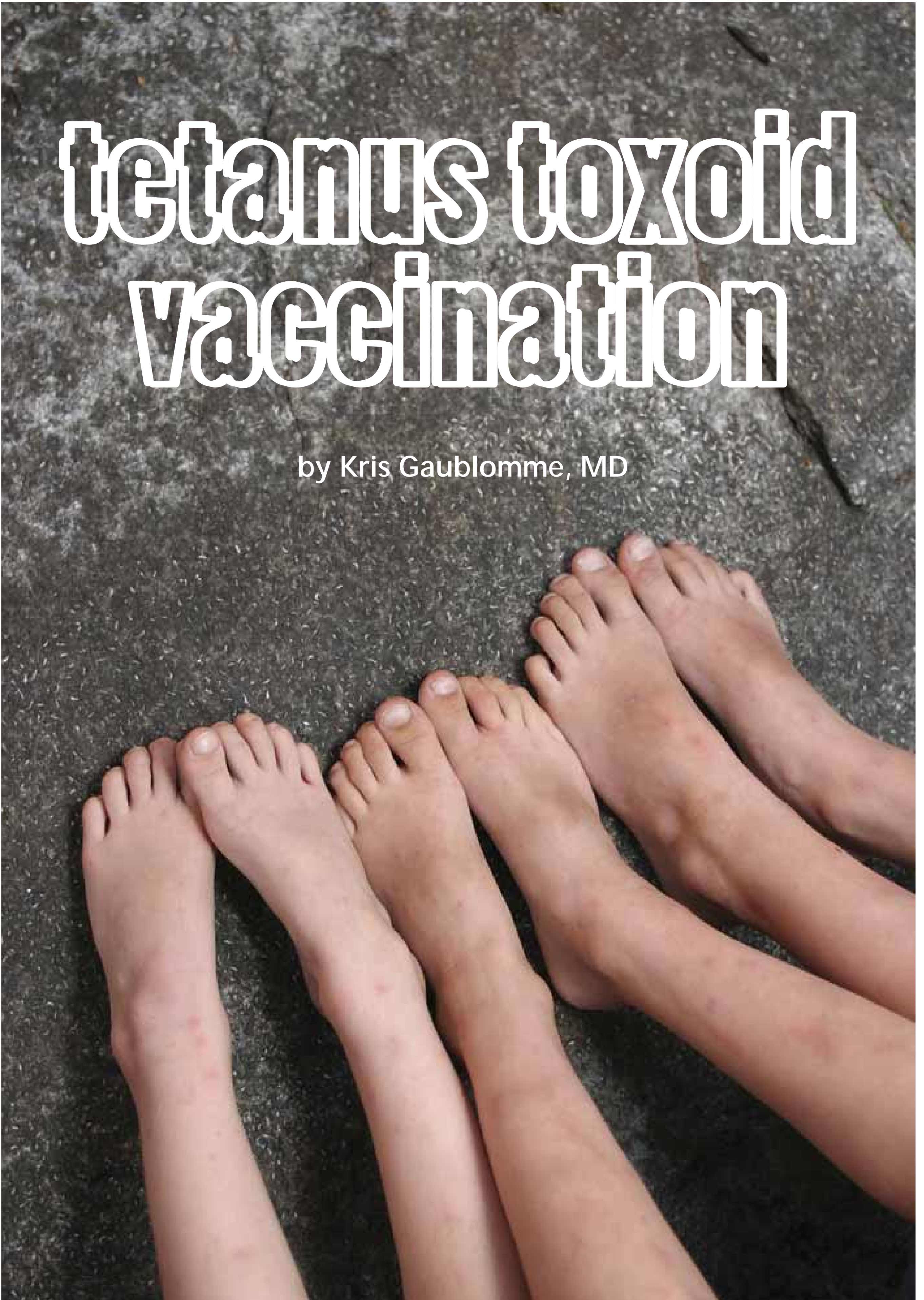
In 1968, the National Communicable Disease Center, USA, mentions a case of tetanus in a fully immunised person[11]. Antibodies were below the 'protective' level in a patient after 3 doses of DPT, as discovered by Peebles[7].

Goulon (1972) saw tetanus occurring in 10 out of 64 'immunised' patients[12]; Berger (1978) made observations about tetanus in well-vaccinated patients[13]. Passen & Andersen (1988) relate a case in a 35-year-old man who developed tetanus despite the fact that he was found to have a neutralising antibody level 16 times that considered protective[5]. He was fully vaccinated in childhood and had had boosters up to 4 years before the accident.

Also in 1986, Vieira and colleagues describe tetanus of the facial muscles in an 18-year-old man, fully immunised, with

tetanus toxoid vaccination

by Kris Gaublomme, MD



a booster being administered 6 years previously[6]. Also, Vieira mentions that 2 out of 3 other cases that came to his hospital were partially vaccinated, meaning that 3 out of 4 cases were vaccinated! Crone and Reder (1992)[2] describe three patients with severe tetanus despite high titres of antibodies. In one patient the disease was even fatal. Two of them had received the vaccination 1 year before the disease occurred. One of them had been deliberately hyperimmunised (Ed. note: artificially inducing an overproduction of antibodies) to produce commercial tetanus immune globulin! With one of the patients, the mouse test was negative despite positive serum antibodies, implying that immunity to tetanus toxoid (in the vaccine) was not paralleled by immunity to tetanus neurotoxin (produced during the disease). This raises another important question about the capability of the vaccine to produce immunity against the disease. 'Sufficient' antibody titres are not synonymous with a guarantee of clinical protection.

2. Safety

"Infections and intoxications due to mistakes in the production of the vaccine have played a role since the beginning of its development. Due to technical failure, particles of tetanus remained in the vaccine fluid causing illness and death. ... The use of certain soils makes it possible that the concentration of formalin (Ed note: the formaldehyde component added to many vaccines, one of whose uses is to make the bacteria less likely to cause the disease it is meant to prevent) is insufficient, so that un-detoxified toxoid remains."[10] McComb describes how "in the National Guard, for example, present regulations require a booster dose against tetanus every three years, and, as a consequence, some of the older members often suffer severe and sometimes temporarily incapacitating reactions to conventional doses of tetanus toxoid."[14]

4% of complications end with the death of the patient, 6 % percent cause permanent damage[10]. Side effects occur after boosters as well as after primary vaccination[10].

General reactions

These may not be as rare as usually assumed. Sisk[15] described four general reactions with one fatal outcome in 500 DT vaccinations.

Immune suppression

A very spectacular observation was made by Eibl et al. in 1984[16]. In order to study the effect of vaccination on the T-lymphocyte helper/suppressor ratio, 11 healthy people were given a tetanus booster shot. A significant decrease in the T4/T8 ratio was observed. In 4 of the patients, the ratio even fell temporarily to 1 or lower. This is a situation often observed in AIDS-patients or in people at risk for the condition!

Allergy

Allergic reactions after tetanus vaccination occur due to hypersensitivity to any of the components of the vaccine. We do not have to consider the tetanus toxoid only, but also additives such as aluminium hydroxide, formaldehyde and thiomersal.

Acute

Fatal anaphylactic reactions are possible[10]. The tetanus toxoid vaccine became available in 1938. Within 2 years, reports of anaphylactic reactions started to surface. "These reactions occurred with both formalin and alum-precipitated toxoid, and were seen after first, second or subsequent injections."[17]

Cooke and colleagues (1940) have drawn attention to this phenomenon and have described a number of cases[18]. Parish and Oakley (1940) gave a description of anaphylaxis after tetanus vaccination[19]. So did Whittingham, that same year[20].

Cunningham[8] in 1940, reported a recurrent severe anaphylactic reaction after tetanus toxoid injection in a healthy female medical staff member. Three weeks after her first shot, a sudden rigor was followed by an intense urticaria (generalised severe rash) preceded and accompanied by marked skin irritation. Despite this, a second shot was given 6 weeks later, and the patient collapsed within 5 minutes after the shot. After she regained consciousness, there was rigor with vomiting and diarrhoea. The patient felt very poorly afterwards for about 24 hours. The allergy was traced down to Witte peptone, a constituent of the medium in which *Clostridium tetani* was grown. The vaccination

was initiated despite a severe reaction to her preceding diphtheria vaccination.

Apparently, 1940 was a fruitful year for learning how to treat anaphylactic reactions after vaccination. Regamey[21] mentions two cases. One is about a patient who did not react to the first shot, but suffered a shock reaction 4 weeks later, another shock reaction occurred 8 hours after the second shot; the third shot, 6 months later, caused the patient's death within 2 hours due to anaphylactic shock. A second patient, a 44-year-old doctor, died 30 minutes after vaccination.

Prof. Dr. W. Spann[22] (1986) described the case of a 14 year old boy, who suffered nothing but a scratch while playing with a dog. The owner of the dog insisted on tetanus prophylaxis. Five minutes later the boy was dead. Wilson[23] mentions 10 cases in England between 1938 and 1946, 3 after tetanus vaccination and 2 after combined vaccines. Seven out of the 10 were fatal.

The case is quoted by Dittmann of a 16-year-old girl who collapsed 24 hours after vaccination with shock and a complete coagulation deficit. The post-mortem revealed 6 litres of blood in the abdomen. A second case was that of a 34-year-old man displaying severe local reactions 24 hours after the tetanus shot. After another 24 hours he was admitted to hospital with shock. He died during the fourth day after vaccination from lack of coagulation, diagnosed as Lyell syndrome[29],[24].

A 55-year-old man suffered an acute heart infarction after vaccination and died within hours[25]. Other authors confirmed the possibility of a causal relationship between vaccination and heart infarction[26, 27].

Delayed

Most allergic reactions are of the delayed type[10]. Edsa[9] described a number of cases. Skin reactions, such as urticaria[28] and chronic urticaria were described by Steigleder[29], Hollander and Wortmann[30] and Fabry[31]. In this last case, aluminium hydroxide again is supposed to have played a role.

Sweeney reports 3 cases after vaccination, presenting themselves as serum sickness, with local redness, swelling, itching, regional lymphadenitis, fever and polyarthritis[32]. A 49-year-old female developed serum sickness together with an arthus reaction. There was fever, swelling of the joints and the lymph nodes, and a local reaction. The patient had to be hospitalised and needed treatment with high doses of cortisone. Hyperimmunisation was observed[3].

Paralytic polio cases after combined vaccines have been reported[10] as well as sepsis (generalised infection)[10], asthma[32, 40] 2 hours after vaccination. Death is the outcome in 0.4/million vaccinations[10]. Frank[24] mentions a lethal outcome in a person who first developed a local reaction, then swelling of the arm, trunk, neck and head, then shock and Lyell-syndrome[29].

Local reactions

The presence of aluminium hydroxyde in the fluid may lead to increased local reactions to the vaccine[33]. These reactions are more violent if the vaccine has been frozen[10]. They occur more frequently in females[34].

1. SKIN

Reactions at the site of vaccination are not rare. Jet (pressurised) injection leads to complications more often than syringe injection. Bleeding after vaccination is possible.

2. NEUROLOGICAL REACTIONS

Neurological reactions were observed in 1.4/million vaccinations[10]. The peripheral nervous system is affected more often than the central nervous system. The rate of side effects is clearly lower than with the DPT vaccination, but similar to the DT vaccination, with the important remark that, with the latter, the central nervous system is affected more often. The time span between vaccination and complication differs from barely a few minutes for acute allergic reactions, to 12 to 48 hours for delayed allergic reactions, to 4 to 10 days for the onset of neuritis[35]. 43% of cases show their first symptoms within 72 hours.

Peripheral neuropathy occurs in 1.4/million vaccinations[10]. The first symptoms can be observed within 10–14 days. It can be provoked by different mechanisms. In one case, a clear cut causal relationship was established with hypersensitivity to the tetanus toxoid.

Gullain-Barré paralysis (GBS) was seen following tetanus vaccination by Hopf (1980)[36]. Pollard & Seiby observed a patient with three episodes of GBS, each following administration of tetanus toxoid[37]. After each vaccination, the attack came sooner than after the previous one (3 weeks, 2 weeks and 9 days interval). Despite this, vaccination was not terminated!

A bout of multiple sclerosis can be provoked by a tetanus shot[10]. Schabet et al.[38] quote the case of a 50-year-old man who developed MS and multifocal cerebral vasculitis and infarction after simultaneous TBE (tickborne encephalitis) and tetanus vaccination.

Provocation tetanus by vaccination must be considered a possibility. The case described by Passen & Andersen[5] was admitted into hospital with a painful wound, not with tetanus. The patient developed a life threatening attack of tetanus only 24 hours after he was 'prophylactically' vaccinated.

Boosters and hyperimmunisation

Generally, booster shots are recommended for tetanus prophylaxis. The recommendations about the frequency of these boosters have changed throughout the last decades. In earlier times, a booster every 5 years was recommended; later this was stretched to a booster every decade. But once again, even this strategy appears not to be based upon evidence. "The epidemiologic evidence indicates that routine decennial boosters are of marginal value and are not cost effective."[39] Moreover, there is no need for them if the goal is to maintain adequate recall ability of the antibodies; this is no problem for as long as 25 years after previous immunisation[7].

Also, importantly, extensive boosting leads to a less effective immune response. In fact, after 5 injections, the decrease in antibody level is steeper than it is after 4 shots[7].

Frequent boosters also lead to increased risks of side effects. This is why the widespread habit in hospitals and general practices to give a tetanus booster with every injury is not only ineffective but even dangerous. If the immune status is unclear, treatment should be restricted to immunoglobulin, after a blood sample has been taken for evaluation of this status[3]. Peebles explicitly writes: "When there is a valid history of the routine schedule of immunisation outlined, special tetanus boosters on admission to camps, schools and colleges and emergency injections at times of injury should be abandoned, to minimize toxoid reactions."[7] He agrees with the observation that vaccine reactions are often paralleled by a hyperimmune state. Especially the practice of blind repetition of the primary immunisation with three shots has to be omitted in order to avoid hyperimmunisation[3]. There is no scientific basis for this practice, as "booster doses of tetanus toxoid induce anamnestic (cellular memory) increases in antitoxin levels even after intervals of 25 to 30 years."[45] As an alternative, a booster dose at the age of 50 is suggested. Everyday clinical practice, however, is miles away from this.

Werner & Grimm write that in 6-7 year-olds, the antibody level may still be high enough to produce increased reactions to the vaccine[40]. Holliday & Bauer admit that adverse reactions are most likely to occur in persons who have had repeated booster immunisations[41].

Also Baraff et al.[42] and Relihan[43] state that adverse reactions appear to be related to the number of prior immunisations and the level of pre-existing antibody response.

Alternative prevention measures

It would be absolutely wrong and short-sighted to present vaccination as the only means of prevention against tetanus. Infection occurs through defects in the skin or mucosal barriers. Hygienic occlusion of such defects when in contact with potentially infected matter (dust, horse manure) is a first essential measure.

Profound wound cleaning is the next very important measure. Every wound should be allowed to bleed freely, since this eliminates bacteria and infected matter from the wound and supplies oxygen through the bloodstream. It is an inexcusable professional mistake to sew infected wounds. They should be left open to the air until completely clean before being stitched. Application of hydrogen peroxide is another cheap, easy, very efficacious and, thus, essential protection against tetanus infection of open wounds. The only exception is small puncture wounds in which the peroxide will not permeate. Peroxide is the first essential product in every household pharmacy. In order to be effective, it has to be replaced annually.

In the third world, the main occurrence of tetanus is in newborns, by cutting the umbilical string with infected scissors. Here again, proper hygienic measures is all it takes to avoid the problem. "The first (method of preventing neonatal tetanus), which has been the principal means of virtually eliminating the disease in the industrialised world and more recently in the People's Republic of China, is by reasonably strict cleanliness at childbirth, in a sanitary environment, and in particular by hygienic cutting of umbilical cord and hygienic care of the umbilical stump after the birth."[44] And the author adds: "... Nor is maternal immunisation alone an adequate solution. Provision of trained assistance at delivery may be slower in eliminating neonatal tetanus, but it also confers many other benefits in reduction not only of neonatal and maternal septicaemia but of a variety of causes of neonatal and maternal morbidity and mortality." Alternative medicine can be highly effective in preventing the disease. Homeopathic remedies like ledum and hypericum, administered when a wound looks suspicious, have proven to be of great value in the prevention of the disease for more than a century.

Conclusion

The overwhelming amount of literature on tetanus toxoid vaccine adverse side effects and the severity of those complications make it absolutely impossible to ridicule them as rare and benign. Doing so could only demonstrate a profound lack of knowledge of the literature concerned.

Cunningham, Brindle and others insist on having adrenalin readily available when tetanus toxoid is administered, thus admitting that the vaccination is in fact a life-threatening medical intervention, even in apparently healthy individuals. This speaks for itself. Risking one's life by an intervention which is probably ineffective, to avoid a disease which will probably never occur, is not sound medical practice. All it takes, on a world scale, to avoid the majority of tetanus cases is clean scissors to cut the newborn's umbilical cord. Information, soap and hydrogen peroxide might do a far better job than tetanus vaccine. ■

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