

Transscript of the Waisenmedizin Video „Waisenmedizin_01_08_25Min_2018.mp4“

This video was shooten 2018!

The time (hh:mm:ss:msms) can also be seen in the video!

00:00:00:03 - 00:00:46:11

Prof. Dr. Dr. Kurt Wilhelm Stahl

Why is it that diseases that affect the poor go unnoticed by research and industry, so to speak? If you look at history, the beginning of the pharmaceutical industry was in Africa. They were substances that treated infectious diseases that the European colonial rulers did not want to get. Paul Ehrlich's sulfur dyes were the first substances to be tested for the treatment of infectious diseases.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

That's where the origin lies of the pharmaceutical industry. Today we are far from that. Any why is this the case? Because an industry is about profit. When it comes to profit, fraud is not far away. When it comes to fraud, the legislature is called into action. If the legislature is called into action, controls will be increased and controls will cost more.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

This is a vicious circle. Our non-profit association is called Waisenmedizin e.V.. Our work began 15 years ago with an accident in the field of leishmaniasis, research and it ended again in Afghanistan in 2014 with an accidental discovery. I would like to talk about this in more detail now. Orphan medicine refers to orphan diseases, that is, diseases that are ignored by the pharmaceutical industry because they do not promise enough profit in poor countries.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

The NGO's international name is "Promoting Access to Care with Essential Medicine", abbreviated as PACEM. This is a Latin word and stands for the experience that our association has had, namely that basic health care promotes inner peace in a society. As a retired doctor, I went on my first foreign assignment to Afghanistan in 2002, namely to Kabul, together with Afghan colleagues.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

I tried to help with my professional experience in the field of wound care. There was enough work because after the long years of war there were many injured people with festering wounds. And I

found a large hospital in Kabul in a disastrous condition. No windows, poor sanitary facilities. In short, it's a big challenge to work here. In the same hospital where I worked there was also a day clinic run by a Protestant German-speaking Swiss around the "Christ Bearer Brothers". At that point, the Christ Bearer Brothers had already been working in Afghanistan to help patients for over 30 years.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

And they also used Afghan personnel as best they could. They called me when they heard about me and told me that they had wounds of a very special kind to show me. Had I ever seen these? I could immediately say yes. From my tropical medicine lessons during my student time in France, leishmaniasis wounds were quite familiar to me.

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I knew that Leishmaniasis parasites are transmitted by flies when they bite the skin and from there populate the large phagocytes as defense cells of the non-specific immune system and proliferate in them. In doing so, they completely disable these phagocytes to fulfill their key function on the one hand in immune defense and on the other hand in promoting tissue regeneration, which is necessary for wound healing.

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The result of this situation was, or rather still is, that these wounds remain open for more than three months and thus meet the requirements for what we in Western medicine call chronic wounds, where we actually only see such wounds in older patients, while Leishmania wounds occur primarily in young children who are bitten by a fly for the first time and transmit the parasites.

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As early as 2002, it was known that leishmaniasis wounds occur in an estimated 70,000 patients in Kabul during the winter season. Of these, 2,000 were treated by the Christ Brothers each winter season. These wounds are so widespread because the war situation, coupled with poor hygiene and impoverishment of the population, means that the fly that transmits the parasites multiplies in the rubbish and dirt and thus promotes the spread of the disease.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

The scars resulting from chronic facial wounds lead to disfigurement and branding of girls and women. Such a thing

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The scars resulting from chronic facial wounds lead to disfigurement and branding of girls and women. Women branded in this way are not allowed to have children and can be rejected by their husbands. So, they have serious social consequences and lead to social exclusion in a society where women are 100% dependent on men. The World Health Organization, called WHO, recommends chemotherapy with antimony preparations that contain the transition element antimony, which is chemically very close to arsenic, another transition element that is known for its toxicity in a number of compounds.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

That's why antimony preparations are not without side effects, some of which are very serious, if the preparation is administered intra-muscularly or intravenously. At the top of the general frequency related to countries where men dictate women like Afghanistan and Algeria, but in the meantime also due to war, Syria. Including the number of unreported cases, the WHO estimates the frequency of skin leishmaniasis in these countries to be 100,000 to 200,000 cases each year.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

15 years of clinical field research in the Near East have given us the experience and certainty of how to treat skin leishmaniasis more cheaply and efficiently. It starts with the fact that I first introduced wound care to the Christ Bearer Brothers, which is now STANDARD for chronic wounds of the old aged patients. It initially consists of cleaning the wound and then treating the wound using a 'wet chamber'.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

It is an electrosurgical method that uses tweezers to perform basic cleaning by passing a current from one arm to the other. And this current heats the tissue, 'cooks' it and cleans the wound from the ground up. When we practiced this method, we saw that the chronic wound not only cleaned itself in a short time, but also that tissue regeneration began in this wound.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

And we have now published this in two clinical studies and also shown it in images. And the initial results confirm what we found in our clinical studies - that skin leishmaniasis is a wound that should be treated as a wound before thinking about it as a therapy. In 2014, when we were no longer in

Afghanistan, the nurse at the Leishmaniasis Center in Masar made a chance discovery that was particularly groundbreaking for our future work in Algeria.

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He had a patient who had a large wound on his face that spanned almost the entire side of his face. This wound seemed too large for him to undergo electrosurgical wound healing before he dressed this wound. However, he no longer uses the classic plaster bandage or gauze bandage for bandaging, but in the meantime we had developed a film-forming gel that, when applied to the wound, acts as a thin layer of protection as the film on the wound hardens and that the patient can apply it to his wound himself.

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We still call this protective gel LeiProtect today. Surprisingly, the nurse found that this wound could without electrical treatment showed wound healing after 14 weeks. When I was in Algeria in December 2015 and the director of the institute, Dr. As Arad told us about our experiences in Afghanistan, he and I visited the Ministry of Health. We presented our results there and the Algerian Ministry of Health suggested that we carry out a compassion use, as we call it in English, in German we would say a hardship study.

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The compassionate use study referred to the fact that in Algeria, difficult and complex leishmaniasis wounds, particularly those on the face, which cannot be treated with local injections, but instead intramuscular antimony injections must be administered. This has to be done as hospital treatment because of the side effects, and it takes three weeks. So, we suggested to the patients that they try our wound treatment with LeiProtect and Hand Disinfection before they decided to carry out the treatment with antimony injections in the hospital.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

According to our information, 30 patients carried out this wound treatment properly and regularly. Si

00:12:44:18 - 00:13:31:21

Prof. Dr. Dr. Kurt Wilhelm Stahl

According to our information, 30 patients carried out this wound treatment properly and regularly. They had 45 wounds. None of these patients required hospitalization. All of these wounds healed up without chemotherapy. Chemotherapy for leishmaniasis should not be completely rejected because

there are different forms of leishmaniasis. On the one hand, there is a decay of the skin, 95% of all leishmaniasis cases in the MENA area have a decay of the skin, and on the other hand, there is the infection of the internal organs, also known as visceral leishmaniasis.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

95% of all leishmaniasis cases in India have the visceral form and this form – in contrast to the skin leishmaniasis - causes death in 20% of cases. Why should we consider skin leishmaniasis, which doesn't kill you but has serious cosmetic consequences, being so cautious about chemotherapy? From the field of bacterial infectious diseases, we are now familiar with the problem of resistance to chemotherapy.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

If you now believe that this is actually only limited to bacteria, then it is far from the truth. In the meantime, after 60 years, parasites also begin to become resistant to antimony chemotherapy. The consequence of this problem can actually only be that we come up with something completely different, namely to support the body with its own defenses, which are inherent in every individual.

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And this is done based on two measures: on the one hand, prevention and disinfection as hygiene and, on the other hand, a protective bandage on the opening of the skin in order to prevent additional germs from getting into this opening and putting additional strain on the immune cells, which are already weakened by parasites. This principle of hygiene, protection and mouth protection is the principle that we refer to with the word LeiClean, that is, clean leishmaniasis treatment instead of chemotherapy.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

Our guidelines include two components. One is hand disinfection. To do this, approximately three milliliters of an alcoholic solution are poured into one hand. And then these hands are disinfected in a prescribed manner so that there is no place left that the microbes killing alcohol did not cover. And this alcohol has the advantage that it evaporates within seconds and the skin is clean and sterile and dry.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

After disinfection, the patient puts a thick drop of the viscous LeiProtect onto his index finger. This gives him a good feeling and he distributes this gel on the wound into a thin layer that definitely exceeds the actual skin injury. This gel dries into a thin layer on the skin within 20 to 30 minutes and lasts 12 to 24 hours.

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And in order to prevent this layer from breaking down, the patient can apply a new layer to the old one every 12 to 24 hours, depending on the moisture level of their skin. He does this six times in a row. On the seventh day he visits the center and the Leishmania Center carefully removes this film on the skin with a disinfectant solution containing water. When removed, it turns out that the skin has completely closed the wound, this ends the treatment.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

If the wound is not yet closed, a new treatment cycle begins and these cycles last until the skin is completely covered with a skin layer. Medicines receive approval, medical devices receive certification and they have the CE mark on the product label. This certification is a prerequisite for patients to be able to use a medical device for themselves.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

The law states that a medical device that does not have CE certification cannot even be given away for free. Certification requires several prerequisites. Of course, the basic requirement is that the product does not cause any harm. This product does not actually need to be effective in the sense of a drug.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

But the production of the product must be described precisely and not only must it be described, it must also be described and controlled down to the raw materials. This is called a so-called good manufacturing practice. In English, good manufacturing practice (abbreviated GMP). And it took us a lot of effort and effort, an undertaking to find a company, that is certified according GMP and that agree to produce our product in small quantities as we need at the beginning.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

The first process of GMP production of ten kilograms of LeiProtect will cost the, which is legally considered the manufacturer, €9,000, which the pharmacy, as a contract manufacturer, will invoice

to the association. We want to repeat our hardship regulation on a group of 100 patients this fall for the new season in Algeria. The Ethics Committee of the Pasteur Institute has already given the green light and approved this study.

NOTE: Due to political riots the study could not be undertaken.

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It will be a so-called single-arm, non-international study, which in turn refers to patients whose skin, leishmaniasis, lesions cannot be treated locally, but only with intramuscular injections in hospital and we want to check how many patients can be spared this hospital treatment through our local LeiClean treatment, i.e. hands disinfection plus LeiProtect. The Algerian Ministry of Health is very interested in this, but we have had to commit ourselves in a cooperation agreement to applying for a temporary CE certification from the BfArM (*Bundesamt für Arzneimittel und Medizinprodukte in Deutschland, Germany health authority*) in accordance with paragraph eleven of the Medical Devices Act.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

Since these applications are generally only submitted by industrial companies that can later earn money with the means, the costs for a temporary certification can rise up to €10,000. However, we have the chance to ask for a reduction in costs when submitting our application to the BfArM. So we expect to have a financing requirement of at least €10,000 in September this year. We cannot raise this amount from our current club assets.

NOTE: The Germany health authority did wave this cost for our NGO

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Prof. Dr. Dr. Kurt Wilhelm Stahl

It is now our task to find donor sponsors who can provide us with a certain amount not just once a year, but monthly, over this two-year period. Donors who could provide us with €50 per month would be ideal. One club member has already signed up, but most of our club members are retired and cannot raise that much money.

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Prof. Dr. Dr. Kurt Wilhelm Stahl

We are looking for donors who will provide us with a monthly donation amount for two years. And we also say explicitly because we think we could distribute these donations to many people. That every euro donated every month counts for our club.