Time to eradicate HTLV-1: an open letter to WHO

10, May 2018

On behalf of Human T Cell Leukemia Virus-1 (HTLV-1) positive patients, expert clinicians and scientists working in the field of HTLV-1 clinical and laboratory research.

Dear Dr. Tedros Ghebreyesus,

We are writing to you today to ask you to support the promotion of proven effective transmission prevention strategies against one of the most potent human carcinogens, Human T Leukemia Virus subtype 1 (HTLV-1).

As experts in this field, we offer our support to co-develop a WHO HTLV-1 webpage under Health Topics, and a WHO HTLV-1 Fact Sheet detailing specifically HTLV-1 prevention strategies. In addition, we would like to propose that information on HTLV-1 is included and updated on various WHO webpages such as Sexually Transmitted Infections, Blood Transfusion Safety and Breastfeeding.

With this letter, we hope to raise your awareness about several current shortcomings and potential solutions in this field.

Our global community has been slow to respond to the HTLV-1 predicament, a virus transmitted through body fluids, causing significant morbidity and mortality. This is almost certainly due to having to address many other pressing health priorities. However today we are encouraged by the WHO’s mandate to value a healthy sexual life and the availability of many WHO fact sheets on other blood borne and sexually transmitted viruses such as Hepatitis B and C and HIV.

HTLV-1 is transmitted through the same routes as HIV-1 through infected body fluids, via condom-less sexual intercourse (1-4), breastfeeding (5-7), sharing of needles (8-11) and the transfusion (12, 13) and transplantation of infected blood and organ donations (14-17).
Recently published prevalence data from Central Australia (where in some communities 45% of adults live with HTLV-1) (18), Japan (19) and Brazil (20, 21) report the importance of HTLV-1’s sexual transmission. The sexual transmission of HTLV-1 was also highlighted in several presentations at the 18th International Retrovirology Conference in Tokyo in Japan in March 2017 (Satake, M. et al O-1-5, Morita, M. et al P-A-6, Fuchi, N. et al P-A-12) and at the 2017 Australasian HIV & AIDS and Sexual Health Conference in Canberra in Australia (22).

In 2012 Antoine Gessain and Olivier Cassar (23) published a systematic review of available data on HTLV-1 origin and prevalence, which we are drawing upon to provide you with an overview of the word distribution of HTLV-1. It is well understood that HTLV-1 originated from non-human primates. It is an ancient virus and its prevalence is complex, in that it is highly endemic in some parts of the world, but regrettably available surveillance data is not comprehensive, and in many regions, accounting for 6 billion persons, HTLV-1 prevalence remains unknown.

HTLV-1 has been detected in most parts of Africa. In Gabon, a HTLV-1 sero-prevalence of 5–10% has been observed in adults, 1-5% in pregnant women and in some villages up to 25% of older women are HTLV-1 positive. In Nigeria, an estimated 850,000 to 1.7 million people are infected with this virus. In Central African Republic, HTLV-1 infection has been reported in 7% of older, female Pygmies of Southern region.

In Japan, an estimated 0.8 million people are HTLV-1 positive and in Southern regions 30–40% of adults > 50 years of age and up to 5.8% of pregnant women carry this virus.

In Jamaica, the estimated mean HTLV-1 sero-prevalence is 6.1% (1.7–17.4%) in the general population (including older persons) and is as high as 2–3.8% among pregnant women and blood donors. Other Caribbean islands that have been studied have similar prevalence rates.

In areas of Brazil, especially in people of African ancestry, HTLV-1 prevalence has been reported in 1.3% in blood donors, 1.8% in the general population and 1.05% in pregnant women with 33% of their family members including children found to be positive.

In Iran, up to 3% of adults are infected in the Mashad area but HTLV-1 is found across the country.

In Romania, the HTLV-1 prevalence has been reported to be 5.3/10,000 among first-time blood donors, and 3–25% in poly-transfused patients.
In non-endemic areas, due to the migration of people and the sexual transmission of the virus, HTLV-1 and 2 have also been detected. In the UK 20,000 - 30,000 people live with the virus, whilst in metropolitan France an estimated 10,000 - 25,000 people are HTLV-1 infected. In the USA, it is estimates that approximately 266,000 individuals are infected with HTLV-1 or -2, and that 3,600 people with HAM/TSP remain undiagnosed.

In a recent hospital-based cohort study in Central Australia, 635/1889 (33.6 %) tested Indigenous people were HTLV-1 positive. Only one of 77 (1.3 %) children tested positive but with age a sharp increase in prevalence rates were observed (15-29 years, 17.3 %; 30-49 years, 36.2 %; 50-64 years, 41.7 %), reaching 48.5 % in men older than 50 years of age (18).

As with most blood borne and sexually transmitted viruses the majority of HTLV-1 positive people transmit the virus unknowingly and are unaware that they are at risk of developing diseases caused by HTLV-1.

HTLV-1 was the 1st infectious agent discovered to be the direct cause of human cancer and is the most carcinogenic of all oncoviruses (24). HTLV-1 causes Adult T Cell Leukemia/Lymphoma (ATL) which depending on subtype, timing of diagnosis and access to treatment, has a median survival of 8 to 10 months despite all the advances in chemotherapy and supportive therapy (25, 26). The lifetime probability of developing ATL is 4-5 in 100 people infected with HTLV-1 (27, 28), and ATL is attributed to the acquisition of the infection in infancy, through breastfeeding. Thus, it is a preventable malignancy and, in our opinion public health efforts to prevent its transmission should be comparable to other preventable cancers. For instance, the WHO's promotion and prevention strategies to reduce smoking related lung cancers are exemplary (WHO Health Topic: Tobacco), though the lifetime risk of developing lung cancer through smoking cigarettes is only 14: 1000 (29).

In addition, HTLV-1 causes chronic, progressing, disabling and painful conditions such as myelopathy and polymyositis as well as chronic inflammatory pulmonary disease, uveitis and dermatitis (30).

The lifetime risk of HTLV-1-Associated Myelopathy/Tropical Spastic Paraparesis (HAM/TSP) approaches 4 in 100 infected people (31-36), with an average of 8 years delay in diagnosis and treatment due to lack of awareness and testing (37). Patients with HAM/TSP suffer from
decades of progressive walking disability, chronic severe back and leg pain, incontinence and urinary retention, severe constipation and sexual dysfunction, all of which lead to social isolation. HAM/TSP affects both adults and children but mostly women, and has been associated with the acquisition of HTLV-1 through organ donation (17) (18th International Retrovirology Conference in Tokyo in Japan in March 2017: Yuzawa K. et al O-5-7).

Despite its distinct etiology and distinctive pattern there is no International Classification of Disease Code (ICD code) for HAM/TSP, an extraordinary state of affairs for a disease described for the first time by Eric Cruickshank in 1956 (38), linked to HTLV-1 in 1985 and for which WHO has had diagnostic criteria since 1989 (39). Patients living with HTLV-1 and/or suffering from HAM/TSP find this omission incredulous. We truly hope that you can help us rectify this serious oversight in order to reduce the under-diagnosis and under-reporting of this disease.

HTLV-1 was discovered 37 years ago (40), just before the AIDS epidemic. It is acknowledged that HTLV-1 research led to the idea that AIDS might be caused by a new retrovirus and therefore greatly abetted the identification of HIV-1. It is disappointing that despite the significance of HTLV-1 research in the fight against AIDS, in comparison to HIV-1, people who are infected with HTLV-1 have received very little attention in form of publicity, development of international clinical guidelines or financial investment into drug development and clinical trials (41).

Worldwide it is mostly women, who carry the burden of HTLV-1 infection and its associated diseases: Women, who become infected through condom-less sex, and their babies, who are infected through breastfeeding. Therefore HTLV-1 is highly concentrated in families [1:3 to 1:4 of family members carry the virus (42, 43)].

In your speech on 3 July 2017 you fearlessly stated that the WHO is fully committed to 'Every Woman Every Child'. You asked for quality, equity and dignity in services for sexual and reproductive health, equal rights and the empowerment of women, girls and communities. Today we are asking you to include families at risk of HTLV-1 in your list of goals to improve global health.

We would like to support the WHO by using published evidence on HTLV-1’s prevalence and
mode of transmission together with the established understanding of effective transmission
prevention strategies against blood borne and sexually transmitted viruses, to produce a
clear and evidence-based WHO HTLV-1 Fact Sheet, which would inform WHO web-users
world-wide.

A recent review of WHO's website revealed that the information on HTLV-1 could benefit
from an evidence-based update, supported by HTLV-1 experts and patient representatives
living with this virus. We need to visibly share the information that about 80% of HTLV-1
infection is transmitted sexually [4000 cases/annum of sexual transmission in Japan alone
(19)] with most of the remaining 20% of transmission being attributed to mother to child
transmission, predominantly through breastfeeding [up to 32% risk to the infant depending
on the duration of breastfeeding (44)]. We would like to see an emphasis on the fact that
HTLV-1 is highly transmissible through infected blood and that the risk through organ
transplantation may be 100% with 2 out of 3 organ recipients thus infected developing
HAM/TSP within 4 years (18th International Retrovirology Conference in Tokyo in Japan in

So far, an astounding 17 different prevention strategies have been identified to reduce the
risk the transmission of other blood borne and sexually transmittable viruses, such as
Hepatitis B & C and HIV (Table 1) but not for HTLV-1.

**Table 1:** List of potentially available strategies to prevent the transmission of blood borne
and sexually transmitted viruses. There has been a case report of HIV cure through stem cell
transplantation but this intervention is risky, carries considerable morbidity and is not a
realistic option as a global strategy. Legend: Not available = NA; The intervention is available
= ✓; The intervention could be available = (✓); Could be effective but not researched = ?.

<table>
<thead>
<tr>
<th></th>
<th>HBV</th>
<th>HTLV</th>
<th>HIV</th>
<th>HCV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Discovered</strong></td>
<td>1965</td>
<td>1980</td>
<td>1983</td>
<td>1989</td>
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<tr>
<td>Vaccine</td>
<td>✓</td>
<td>NA</td>
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<tr>
<td>Test</td>
<td>✓</td>
<td>✓</td>
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<td>Routine blood product screening</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td>Routine organ transplant screening</td>
<td>✓</td>
<td>(✓)</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Routine antenatal screening</td>
<td>✓</td>
<td>(✓)</td>
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<td>----------------------------</td>
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<tr>
<td>Routine sexual health screening</td>
<td>✓</td>
<td>(✓)</td>
<td>✓</td>
<td>(✓)</td>
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<tr>
<td>Treatment or Cure</td>
<td>✓</td>
<td>(✓)</td>
<td>✓</td>
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<tr>
<td>Mother to child transmission prevention</td>
<td>✓</td>
<td>(✓)</td>
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<td>Partner notification</td>
<td>✓</td>
<td>(✓)</td>
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<td>Needle exchange programs</td>
<td>✓</td>
<td>(✓)</td>
<td>✓</td>
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<td>Condoms</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>Strategies for condom-less anal sex</td>
<td>(✓)</td>
<td>?</td>
<td>✓</td>
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<tr>
<td>Post-exposure prophylaxis</td>
<td>(✓)</td>
<td>?</td>
<td>✓</td>
<td>?</td>
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<tr>
<td>Pre-exposure prophylaxis</td>
<td>(✓)</td>
<td>?</td>
<td>✓</td>
<td>?</td>
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<tr>
<td>Voluntary medical male circumcision</td>
<td>NA</td>
<td>?</td>
<td>✓</td>
<td>NA</td>
</tr>
<tr>
<td>Testing and treating sexually transmitted infections</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Education of medics, patients, population</td>
<td>✓</td>
<td>(✓)</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Total number of widely available interventions</td>
<td>12/16</td>
<td>4/12</td>
<td>16/17</td>
<td>10/13</td>
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</tbody>
</table>

Without a doubt, the availability and level of access to these strategies varies significantly from region to region, but there is a very clear directive from the WHO that they work and should be implemented. Especially in combination, they are so effective that many nations are now planning the eradication of three of these viruses.

There is irrevocable evidence that the transmission of HTLV-1 would be averted by

- using condoms when having sex,
- avoiding the transfusion and transplantation of infected blood and organs,
- advising HTLV-1 antibody positive mothers not to breast-feed their babies (if deemed safe) or reducing duration to 3 – 6 months,
- using sterile needles, and
- by educating healthcare professionals and the population about prevention strategies.
For HTLV-1, some of the aforementioned strategies are implemented inconsistently most probably due to a lack of an international consensus and directive. For example, universal antenatal care (ANC) screening is implemented only in Japan. In Brazil, HTLV-1 ANC screening is recommended in some regions but not necessarily implemented. In the UK, ANC screening is not recommended at all, despite recent evidence that it would be cost effective to identify positive mothers and council against breastfeeding and therefore prevent HTLV-1 transmission and ATL disease in their children long-term (18th International Retrovirology Conference in Tokyo in Japan in March 2017: Malik B. et al O-3-2, submitted for publication). If we add to this the prevention of other HTLV-1 diseases the cost effectiveness would be still greater.

In Japan, it is permitted to transplant HTLV-1 positive organs despite recent evidence showing that 63% of recipients of HTLV-1 positive kidneys developed HAM/TSP [(17), 18th International Retrovirology Conference in Tokyo in Japan in March 2017: Yuzawa K. et al O-5-7].

Nowhere that we know of is HTLV-1 part of routine sexually transmitted infection screening or needle exchange programs despite indisputable knowledge of its mode of transmission.

Here we propose the universal HTLV-1 testing of blood and organ donors, and the prevention of HTLV-1 positive blood transfusion and organ transplantations. We offer to support the WHO to develop a **HTLV-1 Fact Sheet** which provides clear advice that HTLV-1 is an oncovirus and can cause severe inflammation. We wish to inform HTLV-1 infected people that they need lifelong clinical and laboratory monitoring (HTLV-1 pro-viral load, lymphocyte count etc.), so that they are diagnosed early when they develop HTLV-1 diseases, so they can access treatment and clinical trials in a timely fashion. We encourage the WHO to support the recommendation that all people living with HTLV-1 are informed, that HTLV-1 is sexually transmitted and that their partners need to be notified and tested. HTLV-1 positive patients need to be informed that HTLV-1 can be transmitted through breastmilk and we need to advise to have their children tested for HTLV-1.

We are pleased to report that even the variable usage of some of these intervention strategies against HTLV-1 have led to a measurable change in the HTLV-1 prevalence profile. In Japan since the introduction of HTLV-1 ANC in 1987 in the Nagasaki region the HTLV-1 prevalence in mothers has reduced from 7.2% to 1% (http://www.med.nagasaki-
Following the national roll out of ANC screening the mother to child transmission has reduced from 20% to 2.5% in Japan (45). In 2017 Dr Lezin reported a significant reduction in HAM/TSP incidence due to ANC and blood donor screening in the French island of Martinique, in the West Indies (46).

Therefore, we propose a WHO HTLV-1 Vision for the prevention of HTLV-1 transmission:
‘Let’s eradicate HTLV-1 together!’ and a WHO HTLV-1 Mission:
‘Intervention strategies to achieve the eradication of HTLV-1’.

This may be achieved with the implementation of 5 strategies:

Strategy #1 protects the sexually active population:
Routine HTLV-1 testing in sexual health clinics should be available to all attendees. All people diagnosed with HTLV-1 need to be followed up medically and monitored clinically, immunologically and virologically to be able to access treatment promptly. We need to promote CMPC: Counsel & Monitor HTLV-1 positive patients, notify Partners and promote Condom usage. This strategy also supports HTLV-1 positive parents to test their children for HTLV-1.

Strategy #2 protects blood and organ donors and recipients:
We need to test donors and not use products potentially infected with HTLV and make medical follow up and CMPC available to those infected.

Strategy #3 protects mothers, babies and fathers:
We need routine antenatal care testing and advise against breastfeeding by mothers who are HTLV-1 positive where safe, alternative methods of infant feeding are available.
Alongside we need to promote CMPC.

Strategy #4 protects people who inject drugs:
We need to promote HTLV-1 testing and provide free safe needles through needle exchange programmes together with CMPC promotion.

Strategy #5 supports the population and health care providers:
Access to up-to-date and evidence-based **WHO HTLV-1 Fact Sheet** and its diseases will allow health care providers to diagnose HTLV-1 and its diseases more often and in a timely fashion. Informed people are more likely to protect themselves and ask for a HTLV-1 test.

Words are important. We need to change the way we talk about HTLV-1 to increase its visibility and are guided by the beautiful language used for the USA National HIV/AIDS Strategy:

**Vision: International HTLV Strategy**

“Our world will become a place where new HTLV infections are very rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination.”

Thank you for considering our point of view and we are looking forward to hearing from you and to support your efforts to increase the visibility of people living with HTLV-1.

Yours sincerely,

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