

CHLORINE DIOXIDE:

A safe and potentially effective solution to overcome COVID-19

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SUMMARY

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LIST OF ACRONYMS AND ABBREVIATIONS

AEMEMI	Equatorial Association of Specialist Doctors in Integrative Medicine
CDS	Chlorine Dioxide Solution
Cl	Chlorine
ClO₂	Chlorine Dioxide
COVID-19	<u>CO</u>rona <u>VI</u>rus <u>D</u>isease - 2019
ALS	Amyotrophic lateral sclerosis
FDA	<u>F</u>ood and <u>D</u>rug <u>A</u>ministration
H₂O	Water
HCl	Hydrochloric Acid
mL	millilitre
MMS	<i>Master Mineral Solution</i>
NaCl	Sodium Chloride (common salt)
NaClO	Sodium Hypochlorite (Household Bleach)
NaClO₂	Sodium Chlorite (Precursor)
NaClO₃	Sodium Chlorate
NaClO₄	Sodium Perchlorate
NaOH	Sodium Hydroxide
O₂	Oxygen
WHO	World Health Organization
PAHO	Pan-American Health Organization
pH	Potential of Hydrogen
ppm	Parts per million
RNA	Ribonucleic Acid
SARS-CoV-2	Acute Coronavirus Respiratory Syndrome Type 2
FIC	Free and Informed Consent
HIV	Human Immunodeficiency Virus

1. INTRODUCTION

1.1. Background

The COVID-19 pandemic has shocked the world and taken thousands of lives, and as one of the equally negative consequences, the world economy has been compromised. Without doubt, this is a problem that requires an urgent solution and the commitment of everyone, especially health personnel, to find an early solution.

In order to identify a solution to this problem, and also on the basis of the scientific evidence already published and the clinical experiences of the use of chlorine dioxide (ClO₂) by doctors and researchers, we have made an assessment of the main information to support our proposal to use the chlorine dioxide solution (CDS), following the standardized protocol detailed by Andreas Ludwig Kalcker as a safe and effective alternative to fight the SARS-COV2 infection.

A review of the use of chlorine dioxide in the international indexed literature from January to July 2020 was carried out and, as an example, if we analyse only the PubMed (National Library of Medicine 2020) website, we see that using only the descriptor "chlorine dioxide", we have available a total of 1,372 documents dating from 1933 to the date of the survey, 2020 (Figure 1).

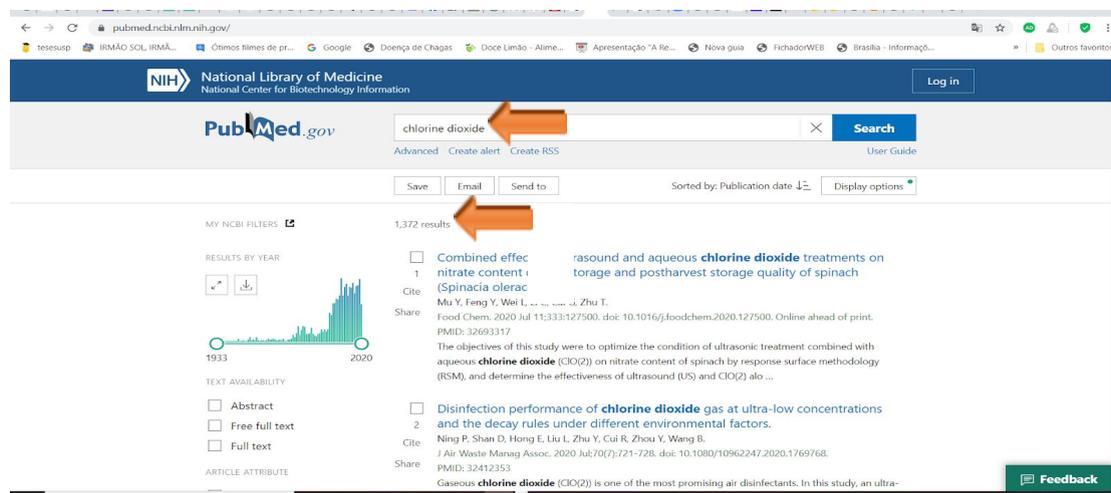


Figure 1 - Number of documents found with the descriptor "chlorine dioxide" in the PubMed scientific database. The orange arrow indicates the descriptor used for the search and the second the number of documents published the 24th of July 2020. Source: <https://pubmed.ncbi.nlm.nih.gov/?term=chlorine+dioxide&sort=pubdate>.

Another important source was the PubChem database (Figure 2), in which it is also possible to identify biochemical and toxicological information among others, and more than 8,000 registered patents. Several patents can also be found at Google Patents, among which the following stand out:

- 1) the patent on the disinfection of blood bags (Kross & Scheer, 1991)
- 2) the patent on HIV (Kuhne 1993);
- 3) the patent for the treatment of neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS), Alzheimer's disease and multiple sclerosis (McGrath MS 2011);
- 4) Taiko Pharmaceutical's (2008) patent for the human Coronavirus;
- 5) the patent for a method and composition "to treat cancerous tumours" (Alliger 2018);
- 6) the patent for a pharmaceutical composition for the treatment of internal inflammation. (Kalcker LA, 2017);
- (7) a patent for a pharmaceutical compound for the treatment of acute intoxication (Kalcker LA, 2017); and;
- (8) a patent on a pharmaceutical compound for the treatment of infectious diseases (Kalcker LA, 2017);
- 9) the patent on the use of CDS for Coronavirus type 2 (Kalcker LA, 2020 - publication pending: /11136-CH_Antrag_auf_Patenterteilung.pdf - restricted archive held by the researcher).

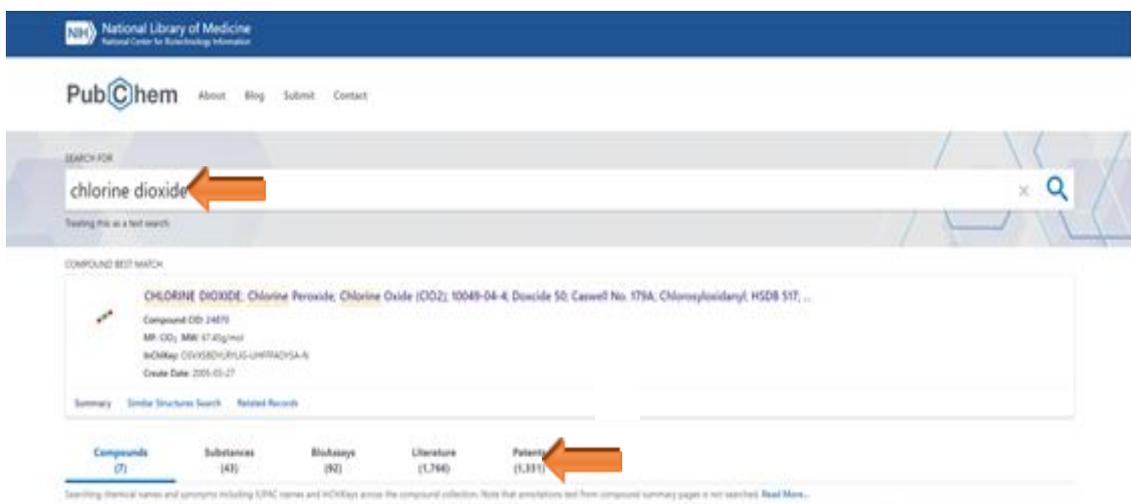


Figure 2 - Number of documents found with the descriptor "chlorine dioxide" in PubChem's scientific database. The first red arrow indicates the descriptor used for the search and the second the number of patents. Source: <https://pubchem.ncbi.nlm.nih.gov/#query=chlorine%20dioxide>. Date of access: 24 of July 2020.

Therefore, with only this initial data, we can see that the research on ClO₂ is far from being a novelty, and that this is a chemical molecule already known for more than 200 years and commercialized for over 70 years with several different uses, namely: water treatment for human consumption, treatment of contaminated water, for the control of biofilm in cooling towers and in food processing and disinfection of vegetables. In addition, pre-clinical and clinical studies have been carried out, as well as studies that allow us to understand their toxicological and safety characteristics, especially regarding human use (Lubbers et al 1984, Ma et al 2017).

1.2. A brief summary on chlorine dioxide

Chlorine dioxide is a gas with a molecular weight of 67.46, a boiling point of 11°C, a solubility in water of 3,000 mg/L at 25°C and a specific gravity of 1,642 at 0°C (Budavari et al., 1989). The chemical formula for chlorine dioxide is ClO₂ and according to the Chemical Abstracts Services (CAS) registry of the American Chemical Society, its CAS number is 10049-04-4. In this formula it is clear that there is one chlorine atom (Cl) and two oxygen atoms (O₂) in one chlorine dioxide molecule. These 3 atoms are held together by electrons to form the ClO₂ molecule. It can be used as a saturated gas in distilled water and can consequently be drunk or applied directly to the skin and mucous membranes with appropriate dilutions for each case.

Biophysicist and Researcher Andreas Ludwig Kalcker has standardised a saturation of gas in distilled water called chlorine dioxide solution or CDS: *Chlorine Dioxide Solution* (National Library of Medicine 2020).

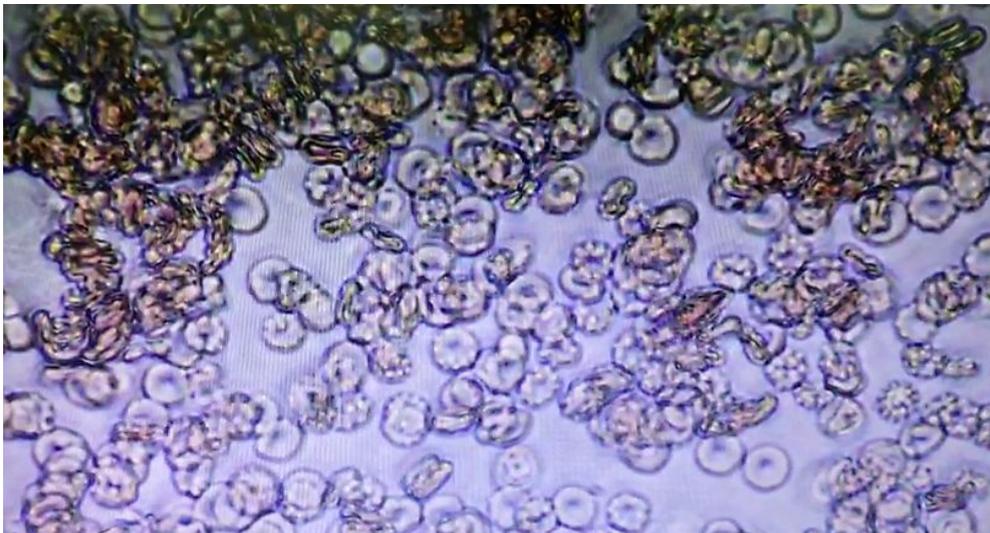
The discovery of the ClO_2 molecule in 1814 is attributed to scientist Sir Humphrey Davy. ClO_2 is different from the chlorine element (Cl), both in its chemical and molecular structure and its behaviour. As has already been widely reported, ClO_2 can have toxic effects in Lungs if the necessary precautions for its various uses are not observed and the appropriate recommendations for human consumption are not followed. It is well known that ClO_2 gas is toxic to humans if inhaled pure and/or ingested in larger quantities than recommended (Lenntech 2020, IFA 2020).

ClO_2 is one of the most effective biocides against pathogens such as bacteria, fungi, viruses, biofilms and other species of microorganisms that can cause disease. It works by stopping the synthesis of proteins in the cell wall of the pathogen. Because it is a selective oxidizer, its mode of action is very similar to phagocytosis, in which a gentle oxidation process is used to eliminate all types of pathogens (Noszticzius et al. 2013, Lenntech 2020). The ClO_2 , generated by sodium chlorite (NaClO_2) has been approved by the United States Environmental Protection Agency (EPA 2002) and the World Health Organization for use in water suitable for human consumption, mainly because it leaves no toxic residues (EPA 2000, OMS 2002).

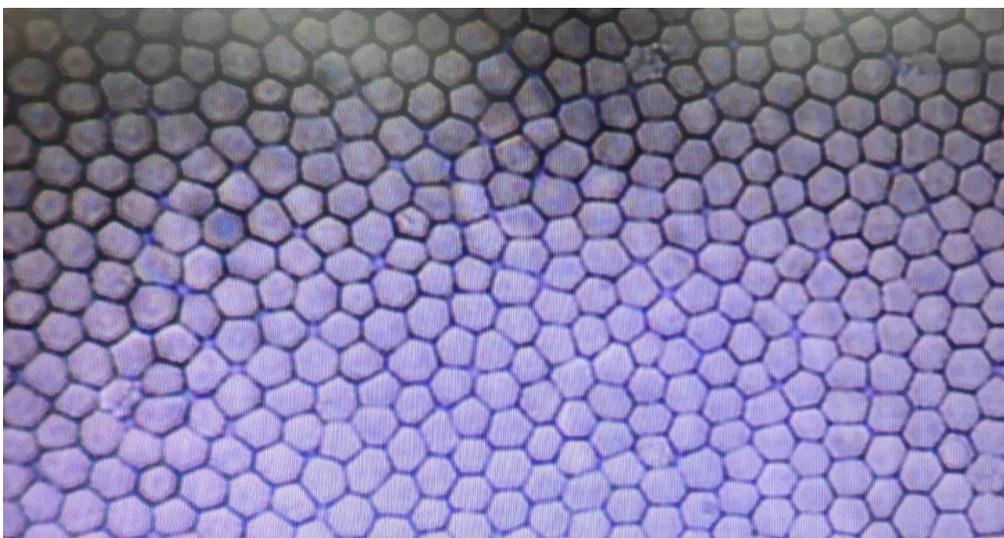
When applied at appropriate concentrations, ClO_2 does not form any halogenated product and its residual ClO_2 by-products are normally within the limits recommended by the EPA (2000, 2004) and the WHO (2000, 2002). Unlike chlorine gas, it does not hydrolyse easily and remains in water as a dissolved gas. Also in contrast to chlorine; ClO_2 remains in molecular form in the pH ranges commonly found in natural waters (EPA 2000, WHO 2002). The WHO and EPA include ClO_2 in Group D (substances not classifiable in terms of human carcinogenesis) (IARC 2001, EPA 2009). According to the 2004 US Department of Health and Human Services, the FDA recommends that the use of ClO_2 should be permitted as a food additive and as an antimicrobial agent (disinfectant).

Many people and even some professionals still confuse and or conflate CDS (ClO_2) with sodium hypochlorite (NaClO - bleach) and the latter with acidified sodium chlorite (NaClO_2) aka MMS

in addition to other chemicals, leading to frequent inappropriate comments both in the media and among professionals due to lack of correct knowledge of elemental chemistry. NaClO (bleach), for example, is a powerful corrosive agent, and the danger caused by chronic and massive exposure to NaClO is well known. It is believed that the symptoms of asthma developed by professionals working in contact with this substance may be due to continued exposure to bleach and other irritants. Thus, it is observed that the main toxicity of the substances generated from the chemical reactions of NaClO is the appearance of a hydroxyl radical NAOH, in the various reactions with the secretions and chemical structure of human tissues (Daniel et al 1990, Racioppi et al 1994; Estrela et al 2002, Medina-Ramon et al 2005, Fukuzaki 2006, Mohammadi 2008, Peck B et al 2011).



Effects on Red blood cells of Hypochlorite (Household Bleach) 5%



Effects on red blood cells of full concentrated **CDS** (aqueous chlorine dioxide) 3000ppm

Gastrointestinal absorption, distribution in the body after ingestion, metabolism, and elimination of chlorine dioxide in the human body.

After ingestion, chlorine dioxide is rapidly absorbed into the digestive tract and peak plasma levels are observed 2 hours after ingestion, and it is estimated that less than 30% of the ingested test dose has been absorbed (Abdel-Rahman et al., 1979a). Once ingested, the compound is distributed throughout the body, but the highest concentrations are found in the blood, stomach, and small intestine (Abdel-Rahman et al., 1982). Seventy-two hours after ingesting a single 100 mg/L dose, most of the chlorine dioxide was detected in the form of chloride ion (Cl⁻), and the chloride-chlorite ratio (ClO₂) was 4 to 1 (Abdel-Rahman et al., 1979b). The chemical form in which chlorine dioxide is eliminated is via urine and faeces. Seventy-two hours after ingestion of marked chlorine dioxide in rats, 10% of it was excreted in urine and faeces respectively, and the proportion of Cl⁻ ClO₂ was 5 to 1 for the first 24 hours and 4 to 1 for the first 72 hours (Abdel-Rahman et al., 1979b).

Based on this brief overview of what chlorine dioxide is and its biocidal capacity, the results obtained by the doctors of the Ecuadorian Association of Experts of integrative Medicine (AEMEMI) in Guayaquil Ecuador, one of the worst COVID affected regions worldwide stand as being not surprising at all: they state that the administration of CDS in appropriate and safe dilutions is a highly effective and low-cost alternative that can quickly contribute to the restoration of the individual's health infected with the human Coronavirus type 2, and it is assumed that it can promote the reduction of morbidity and mortality, **as demonstrated with 104 COVID-19 patients treated with CDS, 97% of which had clear symptoms, and did recover in a matter of only 4 days in most cases(AEMEMI 2020).**

Through evidence from available scientific publications demonstrating the effectiveness of ClO_2 in eliminating different pathogens (Kullai-Kály et al 2020), including SARS-CoV (Tables 1, 2, 3 and 4; Patent Taiko Pharmaceutical 2008), as well as work confirming the safe use of chlorine dioxide for water purification and, more recently, the above-mentioned work of AEMEMI, the use of aqueous ClO_2 solution (CDS) to combat coronaviruses with high biocidal potential is evaluated positively (EPA 2000, OMS 2002, OMS 2005, Ma et al 2007, AEMEMI 2020).

In this context, where the whole planet is in search for an effective solution for the COVID-19 pandemic, we are surprised that official organizations such as Ministries of Health, PAHO/WHO and regulatory agencies and/or health authorities do not recommend the use of ClO_2 at all, instead of researching and recommending it, the attention is drawn to the toxicity and danger of ClO_2 , but they never clearly indicate how and by which route, the administration ClO_2 is actually toxic. However, everything leads us to understand that they refer to the pure and concentrated form of this gas and not to the formula (protocol C) as standardised by Andreas Ludwig Kalcker; being a daily dose of 10 ml diluted in 1 L of water the aqueous chlorine dioxide solution (CDS), at 3000 ppm distributed over 10 single doses. (3mg per dose)

Therefore, to help clarify these concepts, we invite all official bodies to get acquainted with Andreas Kalcker's work dealing with the chlorine dioxide aqueous solution (CDS). Certainly, after having this knowledge, we believe that these bodies, who appreciate health and well being, will naturally understand the potential of this solution for human use, and from then onwards they will be able to review their documents that may be at odds with the published scientific reality and current medical experiences, and perhaps they can offer this information in a clearer and more assertive way in their articles published in the official sites or even in their own documents.

1.3. Key points for reflection

In view of the very serious scenario to which the whole world is exposed because of the current Coronavirus pandemic, we address the authorities and institutions responsible for human health, leading the main institutions, and pose them the following questions:

- ✓ **What can be the purpose/impact of disseminating a document with information that could be misinterpreted?**
- ✓ **Is there a purpose in hiding and/or translating scientific knowledge in a way that causes doubt or harm to the health of thousands of people, and to prevent them from benefiting from something that could actually save lives?**
- ✓ **What is the purpose of not using so-called "unconventional" but potentially promising and clinically proven options for front-line doctors with COVID-19?**

With the legally established purpose of saving lives, it is neither logical nor healthy, let alone a humanitarian and compassionate action, that while the world faces a public emergency, some misunderstandings in the translation of scientific knowledge should occur for any purpose other than the preservation of life. We believe that these concepts that generate misunderstandings can be caused by the lack of knowledge of the existing literature (even if it is open to public consultation). Note: In the PubMed database alone, there are over 1300 documents published using only the descriptor "chlorine dioxide".

Assuming that the team in charge of writing the official documents, the articles, the reports published on the websites of official agencies such as PAHO/WHO in member countries, Ministries of Health and health regulatory agencies, were not aware of the articles and patents (which does not exempt them from legal liability) where the non-toxicity of CDS in the recommended doses is proven, and the possible benefits of chlorine dioxide for human health are stated and that therefore, these responsible teams still don't take into consideration the full potential of ClO₂ as a tool to fight the Coronavirus type 2; the AEMEMI and the team of Doctors and Researchers who sign this dossier take action to invite you to reflect about the following considerations:

- ✓ There are many publicly accessible scientific bases, with many articles available free of charge, containing the necessary information for the production of a document supporting a decision in public management. Why were these bases not consulted or poorly analysed or simply not considered? Why was this not the case? After all, it is an important decision to use or ban a substance for human health in a context of global public emergency to overcome COVID-19.
- ✓ How is it possible for legally responsible official health agencies to take such an important decision without a full analysis of the effects of banning a substance that could simply end the pandemic quickly, safely and effectively?
- ✓ The fact is that any neophyte in the field who reads the various misleading official publications of some health agencies about ClO₂ will naturally be afraid to consume this product because he/she will think that it is toxic and harmful to health, and that it could put his/her life at risk. Similarly, a health professional would also be afraid to use it in his/her therapeutic practice, since the ultimate goal of any health professional is to preserve life and he/she could not offer the patient anything that threatens his/her life.

Based on the dissonant and inconsistent information compared to what is actually and factually known about CDS and its potential, is that we, the health care professionals, intend to give our contribution to health care institutions to review their documentation and the officially published guidelines to promote the clearest and most accurate information on the use, efficacy and safety of ClO₂ for oral human consumption (CDS), as standardized and patented by Kalcker : /CH-713095/CH-713096/CH-713711/,CH-1136-_(pat. pend.) (pdf), we share below a summary of the key scientific facts and evidence that CDS is effective against several pathogens, including human Coronavirus type 2, the etiological agent of it being SARS-CoV2. Unfortunately, the way the information on ClO₂ is disseminated raises questions and, above all, reveals to those who understand the subject from a scientific point of view that the disinformation generated is somewhat surprising.

Trefferliste Registeransicht Was Sie über [diese Trefferliste](#) wissen sollten.

Aktionen

Schutztitel	Info
PDF (A4/hoch), PDF (A4/quer)	PDF aus der Trefferliste erstellen

Suchkriterien

Patenttyp=Alle; Erfinder/in=kalcker

Ergebnisse

Seite 1 von 1 - Treffer 1-3 von 3

Patenttyp	Veröffentlichungs-Nr.	Anmelder/Inhaber/in	Erfinder/in	Veröffentlichte Schriften
CH	713095	Schweizer Zentrum für wissenschaftliche Forschung, Innovation und Entwicklung, Churerstrasse 35, 9470 Buchs	Andreas Ludwig Kalcker, Churerstrasse 35, 9470 Buchs	Patentschrift B1 (30.04.2018) espacenet
CH	713096	Schweizer Zentrum für wissenschaftliche Forschung, Innovation und Entwicklung, Churerstrasse 35, 9470 Buchs	Andreas Ludwig Kalcker, Churerstrasse 35, 9470 Buchs	Patentschrift B1 (30.04.2018) espacenet
CH	713711	Schweizer Zentrum für wissenschaftliche Forschung, Innovation und Entwicklung, Churerstrasse 35, 9470 Buchs	Andreas Ludwig Kalcker, Churerstrasse 35, 9470 Buchs	Patentanmeldung A2 (15.10.2018) espacenet

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1.4. What is Chlorine Dioxide Solution (CDS) and what are the differences with the Mineral Miracle Solution (MMS)

More than 13 years ago, Andreas Ludwig Kalcker began a scientific research to study the applicability of ClO₂ and its dilutions, so that it could be used safely for human consumption. In these studies he developed 4 patents, of which 3 have been published and one is pending approval. These studies are based on the safe toxicity levels established by the German toxicology database Gestis (IFA 2020), and take into account other reference studies already developed, for example, by WHO (2000, 2005) and EPA (2000). These studies confirm the non-toxicity of this gas diluted in drinking water.

Much has been said in the media about the risk of MMS consumption and very often is confused and conflated with CDS. It is important to clarify that MMS is a solution prepared by mixing a few drops of each of the two reagents: sodium chlorite on the one hand, and an acid that can be citric or hydrochloric on the other hand. This mixture is added to a litre of water, placed in a glass bottle, sealed, and consumed orally throughout the day. The problem with this mixture is that neither reagent is chemically pure, nor by ingesting the mixture of these

two reagents (NaClO_2 and HCL) both are ingested as well. Both mix with the precursors generating impurities or chemical by-products having an acid pH that can create discomfort such as diarrhoea, vomiting and other side effects which, although not terribly serious, are nevertheless irritating, especially when taken at very high doses of this product when drinking it. Because of the lack of information that is made available to the general public, in view of the current health emergency; when the public tries to prevent or treat COVID-19, many choose to avoid medical advice or consultation altogether and use products that have not been prepared under the supervision nor manufactured by trained chemists or pharmacists.

On the other hand, the other compound known as the aqueous solution of chlorine dioxide (Also known as CDS), contains only chlorine dioxide dissolved in water at the saturation concentration of 3000 ppm (mg/L) and does not contain sodium chlorite (NaClO_2) contained in the preparation called MMS. In the case of CDS, which is an extremely pure compound, during the manufacture both substances are placed to react in a glass jar containing another small glass beacon where the chemical reaction takes place, and from where the chlorine dioxide gas is generated saturating the water outside the recipient without ever getting in direct contact with it. It is important to clarify without any doubt, that this form of chlorine dioxide in aqueous solution contains absolutely no sodium chlorite, or any acid unlike the commonly used form of chlorine dioxide in the industry. Another way to produce chlorine dioxide is by electrolysis, and in this way no acid is used whatsoever, obtaining a 99,99% pure solution.

Based on the preparation procedure, the CDS solution has a high degree of purity as it contains only chlorine dioxide dissolved in water. In summary, MMS contains impurities that may cause discomfort when ingested, but chlorine dioxide in aqueous solution (CDS) contains only the pure chlorine dioxide gas at a concentration of only 3 g/L dissolved in water and of which only 10 mL are taken to be ingested throughout the day in 10 doses of 1 ml (3mg), dissolved in one litre of cold water. This considerable difference allows the chlorine dioxide solution to be safe and highly tolerable for ingestion in several doses without causing any discomfort or health risks.

It is established that the LD-50 is 292 mg/kg over 14 days (= 20.440mg in a 70kg human) Therefore, as an example, the standardized protocol C by Kalcker which uses 30mg, diluted in 1,000 mL of water, is hundreds of times below the dose being used very successfully by over

3000 Doctors of the COMUSAV in over 20 countries as one of the protocols to combat SARS-COV2. In this specific use -many times below the toxic range- a maximum ingestion of 30 mg/day, divided into 10 doses of 100 mL, is taken, constituting a safe and non-toxic dosage based on recognised scientific references (Ma et al. 2017). In other words, this amount is equivalent to a dose of 15 to 30 mg/day in adult patients with an average weight of 60 kg, a value varying from 0.25 to 0.50 mg/kg/day.

1.5. The unnecessary controversy and its consequences

In the context of the origin of the misguided controversy that has arisen on the issue of "chlorine dioxide", it is important to clarify:

Historically, a product called "miracle mineral solution" (MMS) has been the subject of much controversy in the media around the world because it is sold as non legal "medicine". We often see news on the internet that confuses and or conflates the "miracle mineral solution" with sodium hypochlorite (bleach) (MMS = citric acid + sodium chlorite in water) or with the "chlorine dioxide solution" (CDS = only the pure gas of hydrochloric acid + sodium chlorite in water). The main differences between MMS and CDS can be seen in table 1:

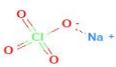
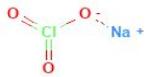
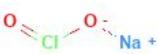
Table 1 – General characteristics that distinguish the miracle mineral solution (MMS) from the chlorine dioxide solution (CDS).

General features	Sodium Hypochlorite (Bleach)	MMS	CDS
ClO ₂ concentration		Unknown	3000 ppm
Ph	13	3,2	7 (neutral)
LD-50	1mg/kg	unknown	292mg/kg
Damaging Residues	THM (cancerous)	Chlorates	none

It is very concerning to witness the consequences and impact of information published in clear dissonance with reality. A failure to translate and correctly interpret scientific knowledge at a time of a global public health emergency when many people's lives are at stake can be fatal. Therefore, it is urgent that all institutions increase their vigilance through the review and prior qualification and evaluation of published information so that there are no flaws in the translation of scientific knowledge, to avoid generating room for doubt and misinterpretation throughout the media, with serious consequences and negatively influencing the decision making of leaders.

If we were to use sodium hypochlorite (NaClO) with hydrochloric acid in water, the solution would contain $Cl_2 + NaCl + H_2O$. Cl_2 is a toxic gas that reacts with organic substances, mainly in aqueous media, where it can form very toxic sub-products. Although biochemical differences are well established, many people still confuse other chemicals with ClO_2 (Table 2):

Table 2: Summary of the main biochemical characteristics of chlorine dioxide and its derived compounds.

BIOCHEMICAL CHARACTERISTICS	CHEMICAL COMPOUNDS						
	Sodium perchlorate	Sodium chlorate	Chlorite from sodium	Hypochlorite of sodium	Sodium chloride	Chlorine	Chlorine Dioxide
Structure							
Chemical formula	$NaClO_4$	$NaClO_3$	$NaClO_2$	$NaClO$	$NaCl$	Cl_2	ClO_2
Molecular weight	122.44 g/mol	106.44 g/mol	90.44 g/mol	74.44 g/mol	58.44 g/mol	70.9 g/mol	67.45 g/mol

Source: PubChem: <https://pubchem.ncbi.nlm.nih.gov/#query=chlorine%20dioxide>.

Date: 24/07/2020.

2. EFFECTIVENESS, SAFETY AND TOXICITY OF CHLORINE DIOXIDE

2.1. Action against viruses

Most viruses behave in a similar way because once they infect the cell, the virus' nucleic acid takes over the synthesis of the cell proteins. Certain segments of the virus' nucleic acid are responsible for the replication of the capsidium genetic material, a structure whose function is to protect the viral genome during its transfer from one cell to another and to assist in its transfer between host cells. When ClO₂ finds an infected cell, a denaturation process very similar to phagocytosis occurs because it is a selective oxidizer (Noszticzius et al 2013).

2.2. Pre-clinical studies

Pre-clinical studies exploring the toxicity of ClO₂ usually find no adverse effects when animals are exposed to different concentrations of this biocide. Here we will refer to some of the most important ones. Ogata (2007) exposed 15 rats to 0.03 ppm ClO₂ gas for 21 days. Microscopic examination of histopathological samples from the lungs of these rats showed that their lungs were "completely normal". In another pre-clinical study, Ogata et al. (2008) exposed rats to 1 ppm ClO₂ gas for 5 hours a day, 5 days a week for a period of 10 weeks. No adverse effects were observed. They concluded that the "no observed adverse effect level" (NOAEL) for chlorine dioxide gas is 1 ppm, a level believed to be non-toxic to humans and exceeding the reported concentration of 0.03 ppm for protection against influenza virus infection.

In studies on rats, Haller and Northgraves (1955) found that long-term exposure (2 years) to 10 ppm of chlorine dioxide has no adverse effects. However, rats exposed to a high concentration of 100 ppm showed an increased mortality rate.

Musil et al (2004) reported that high doses (200-300 mg/kg) of the precursor (!) sodium chlorite caused haemoglobin oxidation to methaemoglobin. However, when the rats drank water for 40 days with varying levels of chlorine dioxide (ranging from 0.175 to 5 ppm), no change in haematological parameters was observed. In another study, chickens and rats that drank chlorine dioxide daily in drinking water at concentrations as high as 1000 ppm for 2 months did not produce methaemoglobin. Richardson (2004) reported that high doses of oral sodium chlorate (NaClO_3) (**which is a different substance from sodium chlorite - NaClO_2**) produced methemoglobinemia and nephritis (US Department of health and human service, 2004).

Fridliand & Kagan (1971) reported that rats that consumed 10 ppm of ClO_2 solution per month for 6 months **had no adverse health effects**. When exposure was increased to 100 ppm, the only difference between the treatment group and the control group was slower weight gain in the treatment group. In an effort to simulate the conventional human lifestyle, Akamatsu et al (2012) exposed rats to chlorine dioxide gas at a concentration of 0.05 - 0.1 ppm, 24 hours a day, 7 days a week for a period of 6 months. They concluded that exposure of the entire body to chlorine dioxide gas of up to 0.1 ppm over a period of 6 months is not toxic to rats.

High doses of ClO_2 solution supposedly may produce haematological changes in animals, including decreased red blood cell count, methemoglobinaemia and haemolytic anaemia. Reduced serum thyroxine levels have also been observed in monkeys exposed to 100 ppm in drinking water and in the offspring of rats exposed to concentrations of up to 100 ppm per gavage or indirectly through the drinking water (US Department of Health and Human Service, 2004).

However Moore & Calabrese (1982) studied the toxicological effects of ClO_2 on rats and noted that when rats were exposed to a maximum level of 100 ppm via drinking water, neither A/J nor C57L/J rats showed any haematological change. It was also found that rats exposed to up to 100 ppm sodium chlorite (NaClO_2) in their drinking water for up to 120 days, could not demonstrate any histopathological change in the kidney structure.

Shi e Xie (1999) indicated that an acute oral LD50 value (expected to result in 50% of dosed animals dying) for stable chlorine dioxide was >10000 mg/kg in mice. In rats, acute oral LD50 values for sodium chlorite (NaClO_2) ranged from 105 to 177 mg/kg (equivalent to 79-133 mg

chlorite/kg) (Musil et al 1964, Seta et al 1991). No deaths related to exposure were observed in rats receiving chlorine dioxide in drinking water for 90 days at concentrations resulting in doses of up to approximately 11.5 mg/kg/day in men and 14.9 mg/kg/day in women (Daniel et al 1990).

2.3. Clinical studies

According to the US Environmental Protection Agency, the short-term toxicity of ClO₂ has been assessed in human studies by Lubbers et al (1981, 1982, 1984a and Lubbers & Bianchine 1984c). In the first study (Lubbers et al 1981, also published as Lubbers and others 1982), a group of 10 healthy adult men drank 1000 mL (divided into two portions of 500 mL, separated by 4 hours) of a **24 mg/L** solution of chlorine dioxide (0.34 mg/kg, assuming a reference body weight of 70 kg) **with no reported side effects**. In the second study (Lubbers et al 1984a), groups of 10 adult men were given 500 mL of distilled water containing 0 or 5 mg/L of ClO₂ (0.04 mg/kg day assuming a reference body weight of 70 kg) for 12 weeks. In the studies no physiological changes were found in general health (observations and physical examination), vital signs (blood pressure, pulse rate, respiratory rate, and body temperature), serological parameters (including glucose, urea nitrogen, and phosphorus levels), alkaline phosphatase and aspartate, and alanine aminotransferase), serum triiodothyronine (T3) and thyroxine (T4), and haematological parameters (US Department of Health and Human Service, 2004).

Michael et al (1981), Tuthill et al (1982) and Kanitz et al (1996) examined the effects of drinking water disinfected with ClO₂. Michael et al (1981) found no significant abnormalities in the haematological parameters or serum chemistry. Tuthill et al (1982) retrospectively compared data on new-born morbidity and mortality in two communities: one using chlorine and the other using ClO₂ for water purification. In reviewing this study, the EPA found no difference between these communities (US Department of Health and Human Service, 2004).

Haag (1949) exposed groups of mice to ClO₂ in drinking water for two years at concentrations resulting in estimated doses of 0.0, 0.07, 0.13, 0.7, 1.3, or 13 mg/kg/day as calculated by the US EPA. The results did not indicate significant differences in mortality between the control group and the treated group up to the highest level of exposure tested. Survival in the 13 mg/kg/day group decreased significantly. No change was observed related to chlorine dioxide

in the histopathological examination of representative animals (2-6/sex) of each group. For this study they identified a level at which no adverse effect (NOAEL) of 1.3 mg/kg/day and a level of free effect (FEL) were observed, based on a decrease in survival of 13 mg/kg/day. In this study, the NOAEL value was lower than in the study by Daniel et al. (1990), but is still between 3 to 5 times higher than the doses used for prevention or treatment of COVID-19, according to the protocol C of Kalcker.

Bercz et al. (1982) used a bottom-up dosing design in which each animal served as a single own control. Five adult African green monkeys and seven females (*Cercopithecus aethiops*) were exposed to 0.0, 3.5 and 9.5 mg/kg of chlorine dioxide per day. In this study, there were no significant changes in either clinical haematological chemistry (erythrocytes, total and differential leukocytes, reticulocyte count, haemoglobin levels, haematocrit, osmotic fragility, and methaemoglobin) or clinical serum chemistry (creatinine, blood urea nitrogen, alkaline phosphatase, lactate and alanine dehydrogenase, and aspartate aminotransferase) or body weight gain. Serum T4 levels decreased significantly in monkeys exposed to 9.5 mg/kg of chlorine dioxide per day. Thus, this study identifies a NOAEL of 3.5 mg/kg/day and a LOAEL of 9.5 mg/kg/day for changes in thyroid hormone levels in monkeys exposed to chlorine dioxide in drinking water for 4-6 weeks. For this study, NOAEL, which is the lowest level at which adverse effects are 3.5 mg/kg/day, i.e. 7 to 14 times higher than that used to prevent or treat COVID-19, as proposed by Kalcker.

In another study, Kurokawa et al (1986) noted that survival was not adversely affected in rats that received the precursor sodium chlorite in drinking water at concentrations that resulted in estimated doses of chlorite up to 32.1 mg/kg/day in males and 40.9 mg/kg/day in females". The exposure of rats to sodium chlorite for up to 85 weeks at concentrations which resulted in estimated doses of chlorite of up to 90 mg/kg/day did not affect survival.

According to Lubbers et al 1981, there were no signs of adverse effects on the liver (as evaluated in serum chemistry tests) in adult men who consumed ClO_2 in aqueous solution, resulting in a dose of approximately 0.34 mg/kg, nor in other adult men who consumed approximately 0.04 mg/kg/day for 12 weeks. The same researchers administered chlorite to healthy adult men and found no evidence of adverse liver effects after each individual consumed a total of 1,000 mL of a solution containing 2.4 mg/L of chlorite (approximately

0.068 mg/kg) in two doses (separated by 4 hours), or in other normal or G6PD-deficient men who consumed approximately doses of 0.04 mg/kg/day for 12 weeks (Lubbers et al 1984a, 1984b). **No signs of deterioration of liver function induced by ClO₂** or chlorite were observed among rural villagers who were exposed for 12 weeks to ClO₂ in drinking water at weekly measured concentrations of 0.25 to 1.11 mg/L (ClO₂) or 3.19 to 6.96 mg/L (chlorite) (Michael et al. 1981). In this epidemiological study, the levels of ClO₂ in drinking water before and after the treatment period were <0.05 mg/L. The chlorite level in drinking water was 0.32 mg/L before treatment with ClO₂. Within one and two weeks after stopping the treatment the chlorite levels dropped to 1.4 and 0.5 mg/L respectively.

In its official document entitled "Laboratory Biosafety Manual" (page 93), the WHO (2005) talks about the ClO₂ (without mentioning the novel pure gaseous form used by Kalcker):

*"Chlorine dioxide (ClO₂) is a powerful germicide, disinfectant and fast acting oxidizer that is generally active in concentrations below those required for chlorine disinfection. The gaseous form is unstable and decomposes into chlorine gas (Cl₂) and oxygen gas (O₂), producing heat. However, ClO₂ is water soluble and **stable in aqueous solution**.*

It can be obtained in two ways:

1) By generation on site, by mixing two different components, hydrochloric acid (HCl) and sodium chlorite (NaClO₂), or

(2) Ordering the stabilized form, which is activated in the laboratory when necessary.

ClO₂ is the most selective of the oxidizing biocides. Ozone and chlorine are much more reactive than ClO₂ and are consumed by most organic compounds. In contrast, ClO₂ reacts only with reduced sulphur compounds, secondary and tertiary amines and other very low and reactive organic compounds. Therefore, a more stable residue can be obtained with ClO₂ in much lower doses than when using chlorine or ozone. If properly generated, ClO₂, due to its selectivity, can be used more effectively than ozone or chlorine in cases of higher organic matter loading".

Based on the WHO Strategy on Traditional Medicine 2014-2023 (WHO 2013), which recognises practices related to traditional, complementary and integrative or 'non-conventional' medicine as an important part of health services, in order to continuously integrate them with the various member countries signatories to this initiative. We put here the potential of the aqueous solution of chlorine dioxide, standardized by Kalcker as a powerful biocide and

therefore as a complementary and safe alternative to combat SARS-CoV2. ClO₂ can combat viruses by the process of selective oxidation through denaturation of capsid proteins and subsequent oxidation of the virus' genetic material, rendering it inactive. As there is no possible adaptation of the virus to the oxidation process, it is impossible for it to develop resistance to oxidation of ClO₂, which makes it a promising treatment for any virus strain.

Here are some examples demonstrating that there is scientific evidence that ClO₂ is effective against SARS-CoV-2 Coronavirus and other types of viruses:

- ✓ Wang et al (2005) studied the conditions of persistence of SARS-CoV-2 in different environments and its complete deactivation by the effect of oxidants such as ClO₂;
- ✓ The Department of Microbiology and Medicine at the University of New England has investigated the deactivation of the human and simian rotavirus (SA-11) by ClO₂. The experiments were conducted at 4°C in a standard phosphate-carbonate buffer. Both viruses were rapidly inactivated in just 20 seconds under alkaline conditions, with ClO₂ concentrations ranging from 0.05 to 0.2 mg/L (Chen & Vaughn 1990);
- ✓ Japanese Tottori University evaluated the antiviral activity of ClO₂ in aqueous solution and sodium hypochlorite against human influenza virus, measles, canine distemper virus, human herpesvirus, human adenovirus, canine adenovirus, feline calicivirus and canine parvovirus;
- ✓ ClO₂ in concentrations ranging from 1 to 100 ppm produced powerful antiviral activity, inactivating > or = 99.9% of viruses in just 15 seconds of treatment. The antiviral activity of ClO₂ was approximately 10 times that of NaClO (Sanekata et al 2010).
- ✓ The Italian University of Parma has carried out studies on the deactivation of viruses resistant to oxidizing agents, such as Coxsackie virus, Hepatitis A virus (HAV) and feline calicivirus. The data obtained from the studies show the following: For complete inactivation of HAV and feline calicivirus, concentrations > or = 0.6 mg / L are required. Similar tests for Coxsackie B5 gave the same results. However, for feline calicivirus and

HAV, in low concentrations of disinfectant, it takes approximately 20 minutes to obtain a 99.99% reduction in viral load (Zoni et al 2007);

- ✓ The Institute of Public Health and Environmental Medicine in Tainjin, China, conducted a study to elucidate the mechanisms of deactivation of the hepatitis A virus (HAV) through the use of ClO_2 , observing the complete destruction of antigenicity after 10 minutes of exposure with 7.5 mg ClO_2 per litre (Li et al 2004);
- ✓ The Department of Biology at New Mexico State University (USA) conducted a study on the deactivation of poliovirus with ClO_2 and iodine. It concluded that ClO_2 deactivated poliovirus by reacting with viral RNA and affecting the ability of the viral genome to act as a model for RNA synthesis (Alvarez ME & O'Brien RT 1982);
- ✓ Taiko Pharmaceutical Co. Ltd. Seikacho, KyotoJapan shows in this study that ClO_2 gas in extremely low concentrations, without any harmful effect on human health, produces a strong deactivation effect on bacteria and viruses, significantly reducing the amount of viable microbes in the air in a hospital operating room (Taiko Pharmaceutical 2016).

2.4. Toxicity

The LD-50 (acute toxicity index) toxicity established by the German GESTIS toxicology database for ClO_2 is 292 mg per kilogram during 14 days, while the equivalent in a 70 kg adult would be 20440 mg per 14 days (IFA 2020). According to the US Department of Health and Human Services, ClO_2 acts quickly when it enters the human body. ClO_2 is rapidly transformed into chloride ions, which in turn break down into chloride ions. The body uses these ions for many normal purposes. These chloride ions leave the body in hours or days, mainly through urine (EPA 1999).

The short-term toxicity of ClO_2 has been assessed in human studies by Lubbers research groups and collaborators:

In the first study (Lubbers et al 1981; also published as Lubbers et al 1982), a group of 10 healthy adult men drank 1000 mL (divided into two portions of 500 mL, separated by 4 hours)

of a 0 or 24 mg/L solution of ClO_2 (0.34 mg/kg, assuming a reference body weight of 70 kg). In the second study (Lubbers et al 1984a), groups of 10 adult males received 500 mL of distilled water containing 0 or 5 mg/kg/day of ClO_2 (0.04 mg/kg/day assuming a reference body weight of 70 kg) for 12 weeks. No studies found physiologically relevant changes in general health (observations and physical examination), vital signs (blood pressure, pulse rate, respiratory rate, and body temperature), serum chemical parameters (including glucose, urea nitrogen, and phosphorus levels), alkaline phosphatase and aspartate, and alanine aminotransferase), serum triiodothyronine (T3) and thyroxine (T4), or haematological parameters (EPA 2000).

Ma et al (2017) evaluated the effectiveness and safety of an aqueous solution of ClO_2 containing 2,000 ppm. Antimicrobial activity was 98.2% in concentrations between 5 and 20 ppm for fungal bacteria and H1N1 viruses. In an inhalation toxicity test, 20 ppm ClO_2 per 24h showed no abnormality in the clinical symptoms and/or functioning of the lungs and other organs. A ClO_2 concentration of up to 40 ppm in drinking water showed no subchronic oral toxicity.

Taylor & Pfohl (1985); Toth et al (1990), Orme et al (1985); Mobley et al (1990) studied the toxicity of chlorine dioxide in various organs of the body at different stages of development of the animal specimens studied, and reported a Minimum Observed Adverse Effect Level (LOAEL) for these effects of 14 mg kg⁻¹ day⁻¹ of chlorine dioxide. While Orme, et al. (1985) identified an unobserved Adverse Effect Level (NOAEL) of 3 mg kg⁻¹ day⁻¹. The clinical experience of Latin American doctors over the past six months suggests that the intake of 30 mg per day of chlorine dioxide dissolved in one litre of water, and drunk during ten events distributed over the day, is a successful treatment for COVID-19, which is 6 times below the dose considered as a NOAEL. Therefore, the literature review confirms that the use of chlorine dioxide ingested at the dose of 0.50 mg per kg per day does not pose a risk of toxicity to human health by ingestion and represents a very plausible treatment for COVID-19.

The most frequent values in the literature reviewed and cited in this report indicate that the FEL (Free Effect Level) is 27 mg/kg/day, the LOAEL (Lowest Level showing Adverse Effects) is 13 mg/kg/day and the NOAEL (No Observed Adverse Effect Level) is 3.0 mg/kg/day. The protocol suggested by Kalcker (2020) proposes the entry of 10 millilitres of a chlorine dioxide solution at a concentration of 3000ppm, dissolved in one litre of water and drunk during the day, as a

strategy to prevent and treat COVID-19, i.e. the actual intake is 30 mg/day for adults weighing between 50-80 kg. If we consider an average weight of 60 kg and the dose ingested is 0.5 mg/kg/day, this represents 6 times below the dose considered as NOEAL. On other occasions, the preventive dose for unexposed or very small exposure has been reduced to only 5 mL of 3000 ppm per day, which represents an intake of only 0.25 mg/kg/day.

Therefore, the literature review confirms and demonstrates that the use of ingested chlorine dioxide at a dose of 0.25 to 0.50 mg/kg/day does not pose a risk of toxicity to human health. Thus, drinking water with CDS suggested as antiviral therapy by Dr. Andreas Ludwig Kalcker and confirmed by an observational study of AEMEMI is 30 ppm/day, for an average of 14-21 days.

The more than 14.000 cases registered by over 3000 Medical Doctors of the COMUSAV association have not reported any serious side-effects in 6 months of use with 100% efficiency treating Covid-19 patients diagnosed with PCR tests.

The results can be seen in Bolivia where CDS has been approved by law starting in September 2020. This country had 100 death cases a day at the beginning of November and now it has been reduced to 6 cases and the town of San Juan de Chiquitos was the first locality worldwide to use CDS on a large scale, ending the pandemic completely within its confines.

3. RECOMMENDATIONS, PRECAUTIONS AND CONTRAINDICATIONS AFTER MEDICAL EXPERIENCE

After the medical experience gathered, we have decided to make the following recommendations:

- ✓ In order to generate chlorine dioxide, the mixture between sodium chlorite (NaClO_2) and an activator (hydrochloric acid) is employed to make CDS where the chlorine dioxide gas saturates water getting a neutral pH; The ideal form is obtained via electrolysis without the need of HCL use;
- ✓ We do not recommend under any circumstance for anyone to ingest sodium hypochlorite (NaClO) or any other chemical product;
- ✓ Do not inhale high levels of chlorine dioxide gas for a long period of time as it may cause throat irritation and breathing difficulties. In small amounts and for a short period of time it is harmless, as shown in Dr. Norio Ogata's studies;
- ✓ Preferably, do not mix CDS with coffee; alcohol; bicarbonate; vitamin C; ascorbic acid; orange juice, or preservatives or supplements (antioxidants). Although they generally do not interact together, as antioxidants they may neutralize the effectiveness of chlorine dioxide;
- ✓ We recommend the intake of healthy foods both in terms of content and quantity;
- ✓ Chlorine dioxide (ClO_2) should preferably be administered in Covid-19 cases, always by prescription and with a medical follow-up, bearing in mind that **self-treatment is not promoted**.

4. LEGAL FACTS AND HUMAN RIGHTS

4.1. International Scope

Scientific advances and discoveries are constant and, in the field of health, immediate access to these by health personnel and patients becomes essential and urgent. It is logical and should be mandatory, out of a pure humanitarian sense and in accordance with scientific rigour, to test substances such as chlorine dioxide (ClO₂) for which there is prior proven evidence of its effectiveness and usefulness. In the history of medicine, the criterion of "compassionate recourse" has always prevailed over the criterion of "perfectly proven resource".

Articles 32 and 37 of the 1964 Declaration of Helsinki allow for this in the case of an "Unverified Intervention" (UI), "When in the care of a patient there are no proven interventions, or other known interventions have proved ineffective, the doctor, after seeking expert advice, with the informed consent of the patient or of a legally authorised representative, may be authorised to use unproven interventions if, in his/her opinion, this gives some hope of saving lives, restoring health or alleviating suffering".

Doctors, according to the Geneva Declaration of 1948, before patients whose health and life are in danger, have the obligation to use all means and products at their disposal which might offer signs of efficacy and, to a greater extent, in a medical emergency, since, and in accordance with the duty of fraternity and humanitarian aid, the use of chlorine dioxide (ClO₂), the non-toxicity of which has been thoroughly documented and whose efficacy and safety have been demonstrated in studies and practices carried out in different countries, should not be limited or denied. To the same extent, States, Institutions and Organizations should not restrict or prevent its use in the face of existing clinical evidence, as they would otherwise fail to meet the obligations assumed in international and national treaties, incurring in the

violation of fundamental rights such as the right to life and health, as well as the right to self-determination of the patient and to professional autonomy and clinical independence.

According to the above, the practice of the medical profession implies a vocation of service to humanity, its main concern being the health and life of the patient, and it must take care of the interests of the citizens, placing medical knowledge at their disposal within the framework of professional autonomy and clinical independence. Within the current legal framework, which is fully applicable and enforceable, the medical profession must have professional freedom without interference in the care and treatment of patients, having the privilege of using its professional judgement and discretion to make the necessary clinical and ethical decisions.

Doctors are legally endowed with a high degree of professional autonomy and clinical independence and are therefore able to make recommendations based on their knowledge and experience, clinical evidence and holistic understanding of patients, including what is best for them without undue or inappropriate external influence, and to take appropriate steps to ensure that effective systems are in place.

Every patient has the right to be seen by a doctor who knows he or she is free to give a clinical and ethical opinion, without any outside interference. The patient has the right to self-determination and to make free decisions about himself/herself. In the free exercise of their right to autonomy, patients have the right to dispose of their bodies, and their decisions must be respected, and they must be fully protected against the intervention of others on their bodies without their consent, and they must be adequately informed about the purpose of the intervention, its nature, its risks and its consequences.

The right to health requires governments to fulfil their obligations under the Covenants/treatises etc. so that health goods and services are available in sufficient quantity, with public access, and of good quality, as set out in the Committee's General Comment 14 on the Covenant on Economic, Social and Cultural Rights.

All of this is covered by the provisions listed below, the essential content of which is summarised;

- Universal Declaration of Human Rights, December 10, 1948.
- American Declaration of the Rights and Duties of Man, Bogotá, 1948.
- American Convention on Human Rights, San José, Costa Rica, November 7-22, 1969.
- International Covenant on Economic, Social and Cultural Rights, December 16, 1966.
- The Convention for the Protection of Human Rights and Fundamental Freedoms, Rome, November 4, 1950.
- International Covenant on Civil and Political Rights of December 16, 1966.
- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, April 4, 1997, Oviedo Convention.
- Nuremberg Code of Ethics of August 19, 1947.
- Geneva Declaration of 1948.
- International Code of Medical Ethics of October 1949.
- Declaration of Helsinki, adopted by the 18th World Medical Assembly in 1964.
- Belmont Report of April 18, 1979.
- WMA Lisbon Declaration on the Rights of the Patient, 1981
- WMA Declaration on Medical Independence and Professional Freedom, 1986.
- Madrid WMA Declaration on Professional Autonomy and Self-Regulation, 1987.
- Seoul WMA Declaration on Professional Autonomy and Clinical Independence, 2008.
- Madrid WMA Declaration on Professional Regulation, 2009.
- WMA Declaration on the Relationship between Law and Ethics, 2003.
- UNESCO Universal Declaration on Bioethics and Human Rights, 2005.
- International Health Regulations 2005.

The International Covenant on Economic, Social and Cultural Rights of December 16, 1966, signed by Ecuador on September 24, 1968, and ratified on June 11, 2010, recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Article 12: "The States Party to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and the duty of the State to protect this right through a comprehensive system of medical care, available to all without discrimination, and accessible to all:

“Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and cooperation, particularly economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including in particular the adoption of legislative measures”

The International Code of Medical Ethics of October 1949, to give effect, among others, to articles 36 and 59 of the above-mentioned text;

Article 36 of Chapter VII on medical care at the end of life.

1. It is the doctor's duty to try to cure or improve the patient whenever possible". When this is no longer possible, the obligation remains to apply appropriate measures to achieve the patient's well-being, even if this may result in a shortening of life.

2. The doctor should not undertake or continue diagnostic or therapeutic actions harmful to the patient without hope of benefit, futile or stubborn. He should withdraw, adjust or not institute treatment when the limited prognosis so advises. He should adapt the diagnostic tests and therapeutic and supportive measures to the patient's clinical situation, and should avoid futility, both quantitative and qualitative.

3. The doctor, after adequately informing the patient, should take into account the patient's willingness to refuse any procedure, including life-long treatment.

4. When the patient's condition does not allow him/her to make decisions, the doctor must take into consideration, in order of preference, the indications previously given by the patient, the previous instructions and the patient's opinion in the voice of his/her representatives. It is the doctor's duty to collaborate with those whose mission is to ensure that the patient's wishes are fulfilled.

Article 59 of Chapter XIV on medical research:

"Medical research is necessary for the advancement of medicine and is a social good that should be encouraged and fostered. Research involving human subjects should be conducted when scientific progress is not possible by alternative means of comparable effectiveness or at those stages of research where it is essential.

The research physician should take all possible precautions to preserve the physical and psychological integrity of research subjects. He or she should take special care to protect individuals belonging to vulnerable groups. The interests of the human being involved in biomedical research should take precedence over the interests of society and science.

Respect for the research theme is the guiding principle of research. Their explicit consent must always be obtained. The information must contain at least: the nature and purpose of the research, the objectives, methods, expected benefits, as well as the potential risks and discomfort that may arise from their participation.

You should also be informed of your right not to participate or withdraw freely at any time from the research, without prejudice.

It is the medical researcher's duty to publish the results of his or her research through the normal channels of scientific dissemination, whether favourable or unfavourable. It is not ethical to manipulate or hide data, whether for personal or group gain or for ideological reasons.

The 1981 WMA Lisbon Declaration on the Rights of the Patient states that “Every patient has the right to be cared for by a doctor who knows he or she is free to give a clinical and ethical opinion, without any outside interference”.

The patient has the right to self-determination and to make free decisions about himself. The doctor must inform the patient about the consequences of his decision.

The mentally competent adult patient has the right to give or not consent for any examination, diagnosis or therapy. The patient has the right to the information necessary to make his/her decisions. The patient must clearly understand the purpose of any test or treatment and the consequences of not giving consent.

The 1986 WMA Declaration on Medical Independence and Professional Freedom: "Doctors should enjoy professional freedom so that they can care for their patients without interference.

The privilege of doctors to use their professional judgement and discretion in making clinical and ethical decisions necessary for the care and treatment of their patients should be maintained and defended. By guaranteeing the independence and professional freedom of doctors to practice medicine, the community guarantees the best medical care for its citizens, which in turn contributes to a strong and secure society”.

The WMA's 2009 Madrid Declaration on Professional Regulation reaffirms the Seoul Declaration on the professional autonomy and clinical independence of doctors, stating that “Doctors are granted a high degree of professional autonomy and clinical independence and are therefore able to make recommendations based on their knowledge and experience, clinical evidence and holistic understanding of patients, including what is best for them without undue or inappropriate external influence”.

The universal principles that permeate all regulations must be fulfilled with respect to innate humanitarian laws in the collective unconscious, as declared in the maxim of the Hippocratic oath "MAINTAIN maximum respect for human life from its beginning, even under threat, and not use medical knowledge against the laws of humanity". Ethical values take precedence over restrictive legal provisions, as is well recognized in the 2003 WMA Declaration on the Relationship between Law and Ethics, which states: "Where legislation and medical ethics are in conflict, doctors should seek to change legislation. If this conflict occurs, ethical responsibilities take precedence over legal obligations.

When a patient, faced with an illness, seeks relief or saves his life and asks to try a therapeutic option for which there are indications of usefulness, such as ClO_2 , it is the doctor's duty to support the patient, acquire knowledge, conduct studies and disseminate them in accordance with Article 27 of the 1948 Universal Declaration of Human Rights, for everyone to benefit from scientific progress, information must be freely shared so that it can be disseminated in all countries without restriction, "Everyone has the right to freely participate in the cultural life of the community, to enjoy the arts and to share scientific progress and its benefits”.

5. FINAL CONSIDERATIONS

In view of the historical moment that all humanity is facing with the Coronavirus pandemic and the urgent need to save lives, the recent events related to the treatment of COVID-19 in both the medical and academic fields, and especially being the purpose of this document, which is to provide the authorities with the correct information on chlorine dioxide for correct and safe human use, it is worth considering some fundamental issues related to human rights and medical practice for reflection and consideration:

- ✓ Adherence to any treatment depends on the agreement and tacit collaboration between the parties: the doctor and the patient (or his/her guardian when he/she is in special conditions that do not allow a conscious choice of a medical intervention, for example, situations of memory loss, trauma or induced unconsciousness in children). This agreement is freely and spontaneously agreed;
- ✓ Based on his clinical experience, the physician is free to prescribe what he considers appropriate for the patient, always communicating the correct way to use a medication, the possible benefits and risks of a therapeutic intervention. On the other hand, the patient, based on the explanations given, personal beliefs and complementary information, is also free to accept or not any form of treatment indicated;
- ✓ Medical practice should always be based, whenever possible, on scientific data that supports the diagnostic and therapeutic behaviour employed. However, in situations where scientific evidence is not available or unreliable, it is up to the physician to use his knowledge, previous experience and common sense to conduct the clinical situation in the manner that seems most appropriate. In this case, it is important that the physician asks the patient to sign a Free and Informed Consent (FIC). For this conduct, the doctor relies on the Declaration of Helsinki (Article 37), which states:

“In treating an individual patient, when it is established that no intervention or other known interventions have been ineffective, the doctor, after seeking expert advice, with the informed consent of the patient or an authorised representative, may use an unproven intervention if, in the judgement of the doctor, it offers hope of saving lives, restoring health or alleviating suffering. Such an intervention should be the subject of research to assess its safety and effectiveness. In all cases, new information should be recorded and, where appropriate, made publicly available”;

- ✓ Regardless everything mentioned above, we cannot underestimate the fact that there is still is not enough evidence in the scientific literature to indicate the use of CDS for prophylaxis or for the etiological treatment of cases of COVID-19 of any severity, but we do have for example, the AEMEMI doctors' technical report stating an efficiency of a 97% in the treatment of patients with COVID-19 during 4 days in Guayaquil/Ecuador (AEMEMI 2020). It should be mentioned that so far, the only research group in the world that intends to conduct an international multicentre epidemiological study, is registered under the number NCT043742 at the US National Library of Medicine/National Institute of Health by Dr. Eduardo Insignares Carrione (Genesis Foundation) and entitled "Determination of the Efficacy of Oral Chlorine Dioxide in the Treatment of COVID-19" (<https://clinicaltrials.gov/ct2/show/study/NCT04343742>) and so far, he has not been able to commence work because regulatory institutions are conveying the wrong message by declaring chlorine dioxide to be toxic;
- ✓ In the specific case of ClO₂, the information and clinical evidence currently available points unmistakably to the effectiveness of this substance for fighting the coronavirus disease (AEMEMI 2020).

In summary:

In view of the above, based on the evidence presented here with evident experiences by scientists and health professionals, as already well demonstrated in scientific articles already published along with the results obtained in Bolivia, we recommend the use of chlorine dioxide solution (CDS) as standardized by Andreas Ludwig Kalcker

(2017), properly diluted and therefore respecting the safe doses of what is already known to be safe from the toxicity studies standpoint, which according to reports from doctors in several countries has proven to be safe for human consumption and also effective against COVID-19 when correctly consumed, following the internationally standardized protocols.

On the basis of this review, we ask the Pan-American Health Organization/World Health Organization (PAHO/WHO) to **revise and withdraw officially** the contents of:

Webinars:

Organización Pan-Americana de la Salud/Organización Mundial de la Salud. **Toxicidad del Dióxido de Cloro.**

Available at: <https://www.campusvirtualesp.org/pt-br/node/29143>.

Organización Pan-Americana de la Salud/Organización Mundial de la Salud. **Dióxido de Cloro: ¿Qué perdemos con probar? El respeto de los derechos de los pacientes.**

Available at: <https://www.campusvirtualesp.org/pt-br/node/29285>.

Official document:

Organización Pan-Americana de la Salud/Organización Mundial de la Salud. **COVID-19: La OMS no recomienda tomar productos que contengan dióxido de cloro, clorito de sodio, hipoclorito de sodio o derivados.**

Available at:

https://iris.paho.org/bitstream/handle/10665.2/52484/OPSIMSPHECOVID-19200040_spa.pdf.

In addition, we hope that it is clear that PAHO/WHO can use as an example the situation that now occurs in Bolivia for the conscious and compassionate use of chlorine dioxide (ClO₂). After a long process of debate and resolution within the framework of human rights exercises and the Law of Participation and Social Control, the population has demanded, through its departmental representatives and the National Assembly, the law that allows the authorization of the production, distribution with quality control and compassionate use of chlorine dioxide. In La Paz, and the law was enacted on September 9, 2020.

In this context, I propose to the PAHO/WHO to convene an international seminar with all Latin American countries to exchange clinical, scientific and management experiences, with the presence of the PAHO/WHO and other entities and actors they deem necessary here in Brazil. Doctors in several countries are using the aqueous chlorine dioxide solution (as standardized by Andreas Ludwig Kalcker) as an alternative for the treatment of individuals infected with COVID-19 with great success.

6. REFERENCES

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7. ANNEXES

Experience Report: The case of Bolivia

BACKGROUND

The Epidemiological Surveillance activated in the country for COVID-19 determines the intervention of the health system in case of suspected and confirmed cases; the attitude of the population is generally to go to a health facility at a late stage with little chance of recovery, considering that we have a cycle of the disease and transmissibility of about 14 days, it does so more or less 4 days after the appearance of symptoms; In addition to this responsibility, the lack of installed means of diagnosis and treatment for the early stages of the disease, the lack of laboratory tests, added to the difficulties of geographical access, have determined the little or no probability of primary and secondary preventive care and consequent treatment with early detection and appropriate containment.

This epidemiological context has allowed a group of independent health professionals to become aware of and contribute effectively to mitigate the transmissibility of SARS-CoV2, adapting to the capabilities of the context and rescuing the experiences of medical professionals with the use of chlorine dioxide that go back more than 10 years throughout the country, facing acute and chronic pathologies; These professionals receive the CDS solution and after informing the patients about its properties and benefits, they ask for the signed consent of the patient to voluntarily agree to the administration of this alternative not included in the package of drugs suggested by the Ministry of Health, whose same government body refers to in these words: "*...The therapeutic indication should consider, at all times, the risk/benefit of prescribing the medicines mentioned above. The possible pharmacological strategies proposed so far are based on studies with a low level of evidence, where confidence in the expected effect is limited, so that the true effect may be far from what is expected, which generates a low degree of recommendation (expert recommendations)*" (Page 52, MINISTERIO DE SALUD, ESTADO PLURINACIONAL DE BOLIVIA, GUIDE TO "EL MANEJO DEL COVID-19, MAYO 2020").

With this certainty, Chlorine Dioxide administration is legally initiated in suspected and confirmed patients of COVID-19.

Two scenarios are contemplated for detection and containment in the Plurinational State of Bolivia: screening from house to house to listen, inform and raise awareness about the importance of blocking the transmission of the disease in the family and community, where the conditions for the care and diagnosis of confirmation do not exist, and even less the basic conditions to follow the recommended actions for hand washing and the use of a mask (real precariousness in distant places of the country), although the attitude of the population in complying with these rules of coexistence is evident.

The other scenario where it was possible to document chlorine dioxide treatment was supported by services (Laboratory and CT) for diagnosis and treatment. In both scenarios, the information and the voluntary decision to sign the Informed Consent was dutifully complied with. (ANNEX No. 37: INFORMED CONSENT FOR THE PHARMACOLOGICAL TREATMENT OF PATIENTS CON COVID-19 (CORONAVIRUS), MINISTERIO DE SALUD, ESTADO PLURINACIONAL DE BOLIVIA, GUIDE TO EL MANEJO DEL COVID-19, MAYO 2020).

KEY RESULTS:

In view of the premise of acting with the screening strategy, we have additionally a number of patients cured and the testimonies that are probably not considered as SCIENTIFIC EVIDENCE per se, but can certainly be considered LIVING EVIDENCE, that the people affected have indeed been cured, and this contributes effectively to the blocking of transmissibility, at least at a family level and for the community at large.

The cases that have been documented are 30 at the moment in the modality of hospitalization, and about 35 in outpatient care. These cases are being documented, compiled and systematized following the requirements of Bioethics and Scientific Studies respecting the structures and procedures for the respective endorsement. As a country, we expect that these processes and procedures of eminent administrative character will adjust to the requirements and innovative demands of timely responses to the current merciless Pandemic.

Of the 30 patients documented that were hospitalized, with a mean age of 51 years (31- 68); 22 men and 8 women; 100% of them have undergone the PCR-RT and/or Elisa Laboratory, Clinical Laboratory, Gasometry and other tests; Regarding the imaging studies, 22 patients have Lung Tomography compatible with COVID-19, "frosted glass pattern in both hemithorax"; Chlorine dioxide was administered orally and intravenously, according to the established protocols. Mean hospital stay was 8 days (range 1 - 31). The origin of the patients (3 men and 3 women), foresaw the adequacy of the protocol in the dosage for intravenous administration (from 10cc to 40cc/1l of Ringer's Lactate to be administered in 12 hrs. These patients came from a mining centre (Height 4,266 m.a.s.l.).

There is a documented case directed to clinical discussion due to the transcendence of a slow recovery after being treated in the Intensive Care Unit, this, together with a control case that they decided to take through conventional treatment, will be attached to the publication of the conclusions to share the experience.

CONCLUSIONS

The death rate in Bolivia went down from over 100 deaths in early September to 6 in early November after implementing the law allowing CDS use, and the cities that have applied it consequently have been infection free for over 1 month.

The more than 3000 doctors of the COMUSAV association that have used CDS as a prophylactic measure did not get infected even in high infection areas, with no reported side effects at all, taking it on a daily basis for several months .

The health personnel, in the context of Medical Ethics and Deontology, assume the responsibility to unite attention to the needs and demands of the population, and in this particular case, the population has demanded the use of Chlorine Dioxide as a preventive and curative treatment. Faced with the lack of control of the pandemic, the representatives of the population (neighborhood and civic councils, grassroots organizations, associations, the Bolivian Workers' Center, the Federation of Bolivian Miners, departmental and national assemblies) proposed to draft, treat and enact the **Law on the Production, Use and Distribution of Chlorine Dioxide (CDS) that has been approved and put into practise nationwide with a very high success.**

Finally, we appeal to all scientific and bioethical societies, as well as academic institutions, to take part in this advance inscribed in the framework of the free exercise of human rights in response to the population's decision to choose, autonomously and fairly, offering solutions to deal with and end this pandemic once and forever.

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