# COGNITIVE AND BEHAVIORAL PATTERNS TOWARDS OZONE THERAPEUTIC MEDICAL APPLICATIONS AMONG HEPATITIS C-POSITIVE PATIENTS

(ANALYTICAL STUDY OF PHYSICIANS` BEHAVIOR AND PATIENTS RESPONSE TO THERAPIES)

#### By

#### Magdi Habachi Mikhail Habachi

Bachelor of Dental Medicine and Surgery,
Faculty of Dentistry, Alexandria University, 1986
Master of Public Health Sciences, Majoring (Nutrition),
High Institute of Public Health, Alexandria University, 1999

A thesis Submitted in Partial Fulfillment of the Requirement for the Doctor of Philosophy Degree in Environmental Science

Department of Medical Sciences

Institute of Environmental Studies & Research

Ain Shams University

#### APPROVAL SHEET

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#### **ABSTRACT**

**INTRODUCTION:** during the last three decades, Hepatitis C (HCV) has emerged as a new biological threat. Descriptive studies were performed in Egypt, between 1999 and 2008 to evaluate the role of ozone therapy for HCV. Whether the disease was in early or late stage, ozone therapy was found to be an effective, safe and, less expensive method in treating hepatitis C patients, used alone or in combination with drug therapy. **STUDY AIMS:** to investigate attitudes among physicians and patients towards HCV conditions, predisposing factors and, different therapeutic approaches including ozone therapy. LITERATURE REVIEW: about the disease condition and proposed alternative cures, SUBJECTS AND METHODS a sample of 92 subjects, forty two physicians and fifty patients, interviewed using two sets of questionnaires, via face to face structured interviews at the site of treatment reception in different localities from Cairo and Alexandria, grouped into three categories, (1) ministry of health governmental organizations and university hospitals (2), army medical facilities (3), private clinics and centers. Snowball sampling method for reaching ozone therapy and, conventional therapists interviewed after obtaining permission from the director of each establishment visited. **RESULTS**: showed negative attitudes towards ozone therapy among our study sample physicians with significant differences when distributed by place of study and physicians specialty. In our study sample 66.7% of physicians believe that ozone is not effective cure and, 69% believe it was banned for pharmaceutical industry conflict of interests. 54.8% assumed that ozone is illegal and unapproved therapy for HCV. Controversially 93.1% of the patients interviewed in governmental organization clinics and university hospitals never received ozone and, 62.5% interviewed in private and army clinics had ozone therapy, and they all had positive attitudes towards ozone therapy for HCV. **CONCLUSION**: with more research needed to elucidate the debate concerning ozone therapy for HCV. **RECOMMENDATIONS:** for the integration of ozone therapies and development of an integrative medical act to be shaped, defined and, incorporated as a complementary and/or alternative, traditional and/or innovative, involving nutritional, psychological and social elements, not to be neglected in the medical practice and curricula.

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#### LIST OF ABBREVIATIONS

AHT AutoHaemoTherapy

BOC Boceprevir

CAM Complementary and Alternative Medicine

CAPMAS Central Agency for Public Mobilization and Statistics

CI Confidence Interval

CIOMS Council for International Organizations of Medical Sciences

CD4 Cluster of Differentiation 4
CPE Cytopathogenic Effect
DAA Direct-Acting Antiviral

DCV Daclatasvir

DNA Deoxyribonucleic acid EHIS Egypt Health Issues Survey

ETR End of Treatment

FDA Food and Drug Administration

G-4 Genome 4

HBV Hepatitis B Virus

HCC Hepatocellular Carcinoma

HCV Hepatitis C Virus

HIV Human Immunodeficiency Virus

IFN Interferon alfa

MOHP Ministry of Health and Population

NCCAM National Center for Complementary & Alternative Medicine
NCCIH National Center for Complementary and Integrative Health
NCCVH National Committee for the Control of Viral Hepatitis

NIH National Institutes of Health PCR Polymerase Chain Reaction

PEG Peginterferon alfa

RBV Ribavirin

RCT Randomized Controlled Trial

RNA Ribonucleic acid SIM Simeprevir SOF Sofosbuvir

SVR Sustained virologic response

TVR Telaprevir

UNITAID UNITAID on Abbreviations.com! 'International Drug Purchasing

Facility

WHO World Health Organization

WFOT World Federation for Ozone Therapy

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#### **Chapter I: INTRODUCTION**

During the last decades, Hepatitis C Viral (HCV) infection has emerged as a new biological threat (Howard, et al., 2012). HCV in Egypt is presented as the most challenging public health problem facing the country, The Central Public Health Laboratory for the detection estimated 3.5 million Egyptians have an active infection. Based on the Deoxyribonucleic acid (DNA) amplification, the Polymerase chain reaction (PCR), allows HCV identification by showing HCV ribonucleic acid (RNA) sequences (Laurent, et al., 1992).

But for HCV there appears to be no such thing as a typical infection.

The severity of the disease varies greatly from person to person and—to the frustration of clinicians and patients— there are few reliable indicators to predict who will do well or badly (Cohen, 1999).

Ozone therapy was found to be an effective, safe and, less expensive method in Hepatitis "C" patients, used alone or in combination with drug therapy and, weather the condition is early or late (Mawsouf et al., 2016).

For many years ozone's medical value or non-value has been the subject of controversial and emotional debate. (Dianzani, 1996), (Tylicki et al., 2004). Leading the ozone opposing argument, is the United States Food and Drug Administration (FDA), who state that: "ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy and in order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals". The FDA approve ozone's use as a disinfectant in the food processing industry and, lists ozone as an antimicrobial agent for bottled water (Petrovic, 2017). However neither the Journal of the American Medical Association (JAMA) nor the Geneva-based World Health

Organization (WHO) had published any research reporting benefits of ozone use in medicine. The updated FDA Code of Federal Regulation states that: "Although undesirable physiological effects on the central nervous system, heart, and vision have been reported, the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema. The onset of pulmonary edema is usually delayed for some hours after exposure; thus, symptomatic response is not a reliable warning of exposure to toxic concentrations of ozone. Since olfactory fatigue develops readily, the odor of ozone is not a reliable index of atmospheric ozone concentration" (US. Code of Federal Regulation, 2017).

While international peer reviewed medical journals lists hundreds of articles published reporting positive outcomes of medical ozone research and application for a range of pathology. Most of these were published since 1990 and are accessible on Medline, and they include pre-clinical studies, animal experiments, patient case histories, placebo-controlled blinded human trials and reviews. The authors are mostly from Italy, Poland, Russia, Germany, Cuba, Spain, Israel, Japan and United States of America, and they draw conclusions that conflict with the FDA. The literature in their native languages is more abundant. Many ozone therapy online articles are intended for professional health providers or those individuals who have had previous knowledge or exposure to ozone therapy information. They tend to discuss more in depth detailed information concerning ozone therapy protocols, biochemical mechanisms and ozone's effects (Schwartz et al. 2012).

Ozone is a well-established alternative and complementary therapy in most mainland European countries where health authorities have tolerated its practice. The European Cooperation of Medical Ozone Societies, founded in 1972, publishes guidelines on medical indications and contraindications of

ozone and hosts training seminars. (**Jacobs et al., 1982**). Today, the basic mechanisms of action of ozone in blood, documenting the existence of a therapeutic window and establishing a framework for understanding and recommending ozone therapy in some diseases have been clarified (**Bocci et al. 1994**).

In general, countries with more socialist-style health systems seem to have had less difficulty in accepting ozone as a medicine. (Madej et al., 1995) No prohibition of ozone therapy is evident in Bulgaria, Cuba, Czech Republic, France, Germany, Greece, Israel, Italy, Japan, Malaysia, Mexico, Poland, Romania, Russia, Switzerland, Turkey, United Arab Emirates and Ukraine. In the USA, the Alternative Therapy Legislation has made ozone therapy an option for patients in some states. In a pioneering way the Egyptian Ministry of Health in December 1999 regularized the practice of ozone therapy by including it in the medical act practice. Despite the progress it reached its end in February 2008 when it banned the practice (Schwartz, et al., 2012). Although ozone is used in a complementary capacity by a significant number of doctors in Italy, Switzerland, Austria and Germany, it has still not gained popular support with mainstream industry policy makers in those countries, it is not covered by health insurance, nor is it part of the curriculum at most esteemed medical schools. Proposals to include ozone therapy in German health insurance schemes invoked hostile objections from pharmaceutical researchers who question its evidence base (Ikonomidis et al.,2005). In the early 1980's, a German survey and investigation into ozone therapy by the University Klinikum in Giessen and the Institute for Medical Statistics, published in the Empirical Medical Acts revealed over 5 million ozone treatments had been delivered to some 350,000 patients, by more than 1000 therapists, of this number about half were medical doctors. Ozone is a natural substance, cannot be patented,

owing to the lack of sponsors and funding, the clinical work, fundamental for demonstrating the validity of ozone therapy, proceeds at a snail pace. The application of ozone in medicine represents one of the most intriguing adventures in research. But clinical scientists for either prejudice, or lack of knowledge, or exclusive interest in pharmaceutical drugs disregard, if not object, ozone therapy that remains in the hands of practitioners who cannot deliver reliable scientific reports (**Bocci et al. 1994**).

"Ozone is safe, effective and useful tool, why not be adopted, applied and approved? But, "both HCV and ozone seem to be controversial issues provoking states of cognitive dissonance".

# **Chapter II: AIM OF THE STUDY**

Our study aims to investigate behavioral attitudes among physicians and patients regarding HCV disease conditions, predisposing factors and, different therapeutic approaches including ozone therapy.

#### **Chapter III: REVIEW OF LITERATURE**

#### **COGNITIVE AND BEHAVIORAL PATTERNS:**

Cognition: is "the mental action or process of acquiring knowledge and understanding through thought, experience, and the senses", (definition of cognition in English from the Oxford dictionary). It encompasses processes such as knowledge, attention, memory and working memory, judgment and evaluation, reasoning, problem solving and decision making, comprehension and production of language. Human cognition is conscious and unconscious, concrete or abstract, as well as intuitive (like knowledge of a language) and conceptual (like a model of a language). Cognitive processes use existing knowledge and generate new knowledge. Within psychology and philosophy, the concept of cognition is closely related to abstract concepts such as mind and intelligence (Blomberg, 2011). In psychology and cognitive science, "cognition" usually refers to an information processing view of an individual's psychological functions. It is also used in a branch of social psychology called social cognition to explain attitudes, attribution, and group dynamics (Sternberg, et al., 2009). In cognitive psychology and cognitive engineering, cognition is typically assumed to be information processing in a participant's or operator's mind or brain (Blomberg, 2011). Cognition can in some specific and abstract sense also be artificial. The term "cognition" is often incorrectly used to mean "cognitive abilities" or "cognitive skills". Metacognition, in a broad sense, is the thoughts that a person has about their own thoughts. More specifically, metacognition includes things like: (1) how effective a person is at monitoring their own performance on a given task (self-regulation), (2) a person's understanding of their capabilities on particular mental tasks and, (3) the ability to apply cognitive strategies. (Martinez, 2006). Common phenomena related to