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## Commentary to Gary Mendell's Article Titled "Addressing the Addiction Crisis during a Pandemic"

Gary Mendell\*

*Department of Public Health and Shatterproof, Cornell University's School of Hotel Administration 7 Corporate Park, CT 06851, USA*

**\*Corresponding author:** Department of Public Health, founder, Chairman and CEO of Shatterproof, Received his B.S. from Cornell University's School of Hotel Administration 7 Corporate Park, 1st Floor Norwalk, CT 06851, USA, E-mail: [gmendell@shatterproof.org](mailto:gmendell@shatterproof.org)

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### Description

The COVID-19 pandemic continues to wear on, and it has changed so much about our lives. For many, it has led to increased isolation, economic struggle, and a newfound, constant uncertainty. As a result, our country's addiction crisis, which was already dire before the coronavirus outbreak, has now become significantly worse.

Over 87,000 drug overdose deaths occurred in the United States in the 12 months ending in May 2020, which is the largest number of overdose deaths ever in recorded history. This compares to approximately 70K for calendar year 2019 when it appeared deaths were leveling off with even a modest decline in 2018. For historical context, overdose deaths in 2000 were approximately 17,000.

Sadly, these figures are just for deaths from drug overdoses and do not take into the account the rising unhealthy relationship and subsequent rise in addiction to alcohol that has occurred over the past year. Pre-pandemic excessive alcohol use was responsible for more than 95,000 deaths a year in the United States alone. The numbers are not known yet, but between February and April of 2020, RTI International's study, found a significant increase in drinking in terms of increasing the number of drinks per day, binge drinking and excessive drinking.

Notably there has been a noteworthy increase in alcohol use disorder and alcohol related deaths in white, non-Hispanic women. Coincidentally, a recent study has shown that alcohol use has risen during the pandemic with greater increase in misuse among women.

Additionally, Express Scripts found that there was a 34% increase in prescriptions for benzodiazepines between February and March. These medications are used to treat anxiety and include Xanax.

It is also important to mention the deadly infiltration of synthetic opioids, notably fentanyl, into our country, which has seriously impacted the number of deadly overdoses.

Our nation is in crisis on many levels and many people turned to substances to cope with their anxieties, fears and uncertainties. Now more than ever people need access to quality addiction treatment.

I know firsthand how deadly a lack of quality care can be. I lost my son, Brian, in 2011, after he cycled through eight different addiction treatment programs. Not one of those programs offered Brain treatment that was based on the most recent science. I know that my family is not alone in our suffering. Each day in this country, hundreds of Americans die from addiction to alcohol and other drugs, leaving hundreds of families shattered. Tragically, the science exists to reduce many of these deaths, but it is not being used.

Shatterproof is transforming the healthcare delivery system via ATLAS®, our quality measurement system, so that every person facing addiction has access to quality care and treatment based on science, just like any other disease. ATLAS will help to transform the treatment system in the United States by delivering valuable information to states, health insurers and treatment facilities to enable data-driven and continuous quality improvement.

Equally important, ATLAS is already helping those searching for treatment for themselves or a loved one locate addiction treatment facilities that provide evidence based high-quality care.

ATLAS has been piloted in six states: Delaware, Louisiana, Massachusetts, New York, North Carolina and West Virginia and will be growing to more states this coming year.

Let's be clear: Addiction is a treatable illness and needs a pandemic-like response immediately.

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# Simulated Clinical User Study Validation of DropSafe Safety Pen Needle

Mariusz Malinowski\*

*Department of Regulatory Affairs, of HTL-Strefa S.A, Adamowek 7, 95-035 Ozorkow, Poland*

\*Corresponding author: Dr. Mariusz Malinowski, Department of Regulatory Affairs of HTL-Strefa S.A, Adamowek 7, 95-035 Ozorkow, Poland, Tel: +48 42 270 02 59; Tel: +48 664 140 193; E-mail: malinowski.mariusz@gmail.com

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## Abstract

Pen needles are essential for drugs injections using pen devices. The use of injection pens with needles sometimes causes accidental puncture. Accidental needle stick injuries (NSI) afflict not only patients, but also impact healthcare professionals who administer medications. The introduction of safety pen needles, with incorporated sharps injury prevention feature, is an advantage over the traditional pen needles reducing the risk of injury and the spread of infectious diseases. This study presents the results of the simulated clinical use study evaluating the safety of the use of DropSafe safety pen needle (SPN), in the prevention of NSI and evaluating the user's satisfaction with regards to the handling characteristics of the product.

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## Keywords:

Accidental blood exposure; Diabetes; Healthcare ;Medical device; Needle stick injury; pen needle ;Safety pen needle; Sharps injury prevention; Blood borne pathogen; Protection

## Abbreviations

ABE: Accidental Blood Exposure; HCP: Healthcare Professionals; NSI: Needle Stick Injuries; NHCP: Non-Healthcare Professionals; IFU: Instructions For Use; SPN: Safety Pen Needle

## Introduction

Accidental Blood Exposure (ABE) is defined as an accident associated with exposure to blood, bloody fluids or other fluids. Examples of the modes of exposure include percutaneous injuries, mucous membrane exposure, and non-intact skin exposure delivered by aerosolization, splash-type events, and piercing of the integument with contaminated objects [1]. ABEs are an inherent risk in that the handling of needles or sharp objects that may be contaminated with blood or other body fluids, and expose healthcare professionals (HCP) and non-healthcare professionals (NHCP) to the risk of serious infection [2,3]. Injuries from non-intentional piercing of the skin with a needle [needle stick injury (NSI)] can occur at various times including during the use of a device with a needle: at the stage of introduction of the needle, at the withdrawal of the needle from the tissue, or other contaminated device, and during the disposal of a device with a needle.

A medical device with a sharps injury prevention feature is a device designed with a component or attachment, either active or passive, that protects the user from a sharps injury. The Drop Safe safety pen needle (SPN) (manufactured by HTL-Strefa, Poland) is designed in a way that sharps injury prevention feature is incorporated as integrated component of finished device.

Pen needles are essential for insulin injections using pen devices. The use of insulin injection pens with needles sometimes causes accidental puncture. Accidental needle stick injuries (NSI) afflict not only diabetics, but also impact health care professionals who inject insulin. NSI may occur while uncapping

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an insulin needle, injected into a person, especially if a skin fold is used, or while recapping. NSI can occur from exposure to the front tip of the needle, or to the back end (cartridge end) of a pen needle. The introduction of SPNs is an advantage over the traditional pen needles and may reduce the risk of injury and the spread of infectious diseases.

Although pen needles with an automatic recapping ability is widely used in clinical practice, there is still no much literature and comprehensive evaluations of this kind of medical devices.

The manuscript of the article presents the results of the simulated clinical use study evaluating the safety of the use of Drop Safe SPN, developed by HTL-Strefa S.A., in the prevention of NSI and evaluating the user's satisfaction with regards to the handling characteristics of the product.

### **Safety Pen Needle Description**

Drop Safe SPN are sterile, single-use safety needles intended for use with pen injector devices for the injection of drugs. The device was designed to minimize the risk from accidental needle sticks with a used needle by application of a sharps injury prevention feature. Following use, the needle is locked out preventing reuse. The shield also serves to hide the needle before and after injection (Figure 1). The Drop Safe SPN is used by attaching it to the pen injector device to administer a drug subcutaneously. While inserting the needle into the skin at a 90° angle, the slider glides into the shield. While the slider glides into the shield, the safety feature is activated. Following injection, the slider glides back into its initial position, completely covering the needle where it remains locked. The red safety lock indicator tells the user that the safety lock has been activated. Once the SPN is in the locked mode, it cannot be reused. The SPN can be then detached from the pen injector device and disposed safely.



**Figure 1:** The needle is locked out preventing reuse.

### **Simulated Clinical User Study Validation**

A simulated clinical user study was designed to evaluate the safety of use of Drop Safe SPN in the prevention of needle stick injuries. The primary objective was to evaluate the number of injuries or non-activation of the safety feature reported by the evaluators for the device. Success was defined as a complete activation of the safety feature following injection without a NSI, whereas failure was defined as NSI or a non-complete activation of the safety feature following injection reported by the evaluators for each device.

The study was designed in accordance with US FDA Guidance for Industry and FDA Staff, “Medical Devices with Sharps Injury Prevention Features, Section 10, Simulated Clinical Use Testing” [4].

In accordance with the FDA recommendations, 540 safety devices (n=540) were tested. Acceptance criteria were defined in accordance with the FDA Guidance [5].

The study was performed in the US by a total of 30 evaluators [6]. The evaluators were composed of 20 non-healthcare professionals (NHCP) and 10 healthcare professionals (HCP) [7]. Of the 540 injections performed with Drop Safe SPN, 180 were performed by a HCP and 360 by a NHCP [8].

To mimic real clinical conditions of device use, HCPs performed injections with gloves and NHCPs without gloves [9]. Injections were performed using an orange. The use of fruit as a model mimicked a subcutaneous (SC) route of administration [10]. For each device, the evaluators were to administer the injection with the Drop Safe SPN and pen injector with a sterile, water-filled cartridge, strictly following the instructions for use [11,12].

The analysis of the injury onset and success of manipulations showed the following results:

- zero injuries and zero failures of the Drop Safe SPN performed by a HCP,
- zero injuries and zero failures of the Drop Safe SPN performed by a NHCP.

Of the 540 simulated injections performed with Drop Safe SPN, zero failures were observed and all manipulations were performed without a needle stick or without contact with the needle after injection [13,14]. In addition, the safety feature of the Drop Safe safety pen needle was activated successfully [15,16]. The failure rate in the validation was 0.6%. According to the tables given in the FDA guidance [17,18], these observations have determined that the primary objective of the simulated clinical user study was achieved for Drop Safe SPN (acceptance criteria is less than 1%) [19,20].

This study not only confirmed the performance of the two versions of the sharps injury protection device but also gave the opportunity to evaluate instructions for use (IFU) for clarity and utility and to capture feedback from the evaluators on several aspects of the safety device and on. The evaluators completed the evaluation questionnaire, using 5-point Likert scale, in which 1=strongly disagree and 5=strongly agree. It was demonstrated (based on the combined rating for the two highest categories: strongly agree and agree) that:

- The label on the seal was legible and properly identified the length of the needle (100% of HCPs and 90% of NHCPs)
- The safety pen needles were easy to attach to the pen (70% of HCPs and 95% of NHCPs)
- Removing the outer cap was easy (100% of HCPs and NHCPs)
- The needle was visible through the viewing window (100% of HCPs and NHCPs)
- Priming test could be assessed through viewing window (100% of HCPs and 95% of NHCPs)
- Injection was easy (100% of HCPs and NHCPs)
- It was clear when safety feature was activated (100% of HCPs and 90% of NHCPs)
- Injection and safety feature activation could be easily performed using one hand (60% of HCPs and 65% of NHCPs)
- Removing needle from pen was easy (90% of HCPs and 100% of NHCPs)
- It was easy to put the needle into the sharps container (100% of HCPs and NHCPs)
- The written instructions were easy to understand (90% of HCPs and 100% of NHCPs)

Taking into account the above-mentioned observations it was demonstrated that:

- No extensive training was needed to use Drop Safe safety pen needle effectively
  - Injection and activation of the needle safety was easy
  - Use of the safety feature was obvious
  - It was clear when the safety feature was activated
  - The safety feature activated only when injection was complete.
-

## Discussion and Conclusion

NSI is one of the most common health hazards in the healthcare setting. The World Health Organisation estimates about 3 million of the 35 million health care workers worldwide are exposed to blood-borne pathogens each year.

It is estimated that there are one million needle-stick injuries a year. Other estimates put the number of NSI per worker healthcare between 0.1 and 0.64 or even be as high as 0.98 per year. Based on the above figures, it is argued that the number of NSIs alone would be between 800,000 and 5,120,000 per year, however, 600,000 reported injuries and 600,000 unreported injuries are more likely. Accidents of this kind were most common in nurses working in dialysis units, emergency rooms, GP surgeries, surgical wards, and operating rooms.

Independent studies showed that the majority of these potentially fatal injuries can be avoided using a combination of training, safer working practices and medical technology incorporating safety features, e.g. needles with automatic protective sheaths .

The most effective way to reduce the NSI prevalence among healthcare workers is to use safety equipment which is easy to use with safety mechanisms that are easy to activate. Pen needles are often implicated in the risk of sharps injury, as they are used widely by diabetic patients, as well as by healthcare workers giving subcutaneous injections to patients. Pen needles with automatic protective safety feature have been found to minimize the risk of exposure to blood-borne infections, such as hepatitis B virus, hepatitis C virus and human immunodeficiency virus, associated with NSIs, without any related adverse event. Recent findings revealed that patients with type 1 diabetes (T1DM) can experience improvement in the level of pen needles usability, HbA1c values, and hypoglycemia after usage of the SPN. The SPN significantly improved usability and reduced the fear of insulin self-injections amongst T1DM patients compared to conventional pen therapy.

The performance and its ease of use, ergonomics and functionality of the device were confirmed and appreciated by users during the simulated clinical user study. Drop Safe SPN was considered to be an effective needle stick protection device, without use problems, which allows an injection to be performed using a one-hand technique, and which does not need extensive training for correct manipulation.

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## Awards 2021 Epigenetics and Chromosome

Elena Wilson

Email id : meevents@conferenceseries.com ;Conference Manager Department of Medicine, USA

### Expert Level :

The Achievement award is designed to recognize sustained, exceptional performance and/or significant contributions of the individuals who have made splendid contributions in Epigenetics. Scientific Service Achievement Award is one of the most distinguished awards in the conference. The applicants should have minimum of 20+ years of experience in the relative field including performance or project goals above and beyond normal performance expectations in public or private sector. The applicants are expected to have a highly committed passion and should take lead in researching the current trends and developments towards the related subjects. The applicants can be nominated through online.

### Professional Level:

The Research Contribution Award aims to recognized renowned professional for their excellence in research in the area of Epigenetics to the advancement of knowledge in their own fields with significant impact on public or private sector. The applicants should have 10+ years in area of Epigenetics with their outstanding achievements. Part-time research experience would be counted as pro-rata. It is calculated starting from the date when you obtained the (first) degree entitling you to embark on a doctorate (either in the country in which the degree was obtained or in the country in which the researcher is recruited), even if a doctorate was never started or envisaged. The applicants can be nominated through online.

### Scholar Level:

Applicants must be upcoming scientist, researchers and experts who possess 10+ years of expertise in the area of Epigenetics. The purpose of these awards is to inspire promising participants to expand their network by widely discussing their research advances and their outcome. Presentation includes 25-30 minutes of oral talk on the scientific research topics based on the theme of the conference along with 5 minutes panel discussions. The applicants can be nominated through online.

### WomenScientist:

Women in Science Award highlight major contributions by female scientists to the science and technology sector. Winners of the award are inspiring role models for future generations of women in science. Through this conference, a launch pad is provided for Women Scientist for presenting their research advances in the area of Epigenetics. As a part of encouragement to women scientist's participants, awards and assistantship for women scholars in career development and research guidance through our collaborations will be given. We cordially invite women scholars and scientists from Universities/ Industries to who have 10+ years of research experience to join the forum. The applicants can be nominated through online.

### Outstanding Speaker:

The conference offers awards to the best Outstanding Speaker based on the scientific content and quality of presentation. The aim of the awards is to support research activities in the field of Epigenetics research and to identify the marvellous work by the participants for presenting their projects, strategies, and schemes that have been implemented to improve long-term excellence in Epigenetics. The applicants can be nominated through online.

### BestKeynoteSpeaker:

This recognition celebrates the most inspiring and effective presentations that are delivered by impactful, confident and engaging speakers. The Awards will be given to the speaker who has made significant contributions advances in their projects, strategies, and schemes and successfully implemented to improve long-term excellence in Epigenetics. The deserving applicants can be nominated through online.

### BestPosterPresentation:

In order to identify best poster presentation from the poster session, student poster competition is organized at Conference. Award should motivate participants to strive to realize their full potential which could in turn be beneficial to the field as whole.

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Editorial

## Awards 2021 Traditional and Alternative Medicine

Milagrosa Chiu Shieh Li,

Email id : dramilagrosa@gmail.com ;Associate Professor, Department of General Medicine, Paris, France

### Expert Level :

This award will be given to the speaker, who has made major long-term achievements or some extracurricular activities in the field of Traditional and Chinese Medicine. The eligibility criterion for this award is the speaker must have 20+ years' experience in different conferences, events related to Traditional and Alternative Medicine. He/She must be a senior Professor, Doctor or any kind of senior industrial expert. Speaker must have published 20+ international papers in different journals. We can nominate this award by online after viewing the abstracts.

### Professional Level:

This award for Professional level will be given to the speaker, who has made some outstanding research (experimental, theoretical and scholarly) or service contribution in the field of Traditional and Alternative Medicine. He/She must be dedicated to his/her research fields or profession. Speaker must have 10+ years' experience in this field. Part-time research experience would be counted as pro-rata. It is calculated starting from the date when you obtained the (first) degree entitling you to embark on a doctorate (either in the country in which the degree was obtained or in the country in which the researcher is recruited), even if a doctorate was never started or envisaged. You can nominate deserving of the award through online. We can nominate this award by online by our scientific committee members.

### Scholar Level:

Traditional and Alternative Medicine 2020 conference offers Scholar Level Award for the Scientists, Researchers, Assistant Professor, Junior Research Group Leaders and Experts who having record of several years of independent academic work or 10+ year's research experience in the field of Traditional and Alternative Medicine & it's related fields. Our conference would like to provide best platform to expand your network by sharing your research knowledge at stage about the Traditional and Alternative Medicine aspects and future research ideas which will helpful for the faster growth. The Presentation includes 25-30 minutes of oral talk on the scientific research topics based on the theme.

### Women Scientist:

Traditional and Alternative Medicine conference provide a unique platform for Women Scientists for presenting their latest research projects with an in-depth analysis. Winners for women of science award will be the inspiring role models for future generations of women. Traditional and Alternative Medicine. We are happy to encourage our women scientist's participants through research awards and provide assistance for women scholars in career development and research guidance through our collaborations. Women Scientist can nominate deserving of the award through online.

### Outstanding Speaker:

This award is recognizing for individual who will present best Oral talk at the conference Venue. Traditional and Alternative Medicine is eligible for this award. They must have to prepare for the conference with good PPT/Videos. Speaker's topic must be interesting and that should have best scope in future. Speakers need to submit their abstracts in the abstract submission page of the conference website.

### Best Keynote Speaker :

This award is recognizes for best Keynote speaker who will present their projects Alternative Medicine. Researchers can choose their topics from the Traditional and Alternative Medicine conference page. If you were confirmed as keynote presenter from the program manager, then you are eligible for this award. We welcome Scientists, Researchers, Assistant Professor, junior research group leaders and experts to define the excellence on the platform, from exemplifying ethical behaviour to selflessly devoting time to make conference memorable.

### BestPosterPresentation:

Student Poster Competition is organized at conference Best poster presentation award is recognizes for the individual who's presentation content provides appropriate perspective context for the subject, objectives / research topic clearly stated and designed well with proper methods, modelling and it will be decided by the Session Chairperson of Traditional and Alternative Medicine .characterization. The awardee will be felicitated after the of the culmination poster session.

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## Awards 2021 Cancer

Ravi Sharma

Email id : dravisharma327@yahoo.com ; Associate Professor, Department of Cardiology, India.

### Expert Level:

The award to the specialists who have made exceptional commitments in plant science. It is the foremost prestigious award of the entire conference and is labelled as scientific service Achievement award. The qualification criteria for accomplishing this award is that one should have least of 20+ years of experience within the relative field in public or private segment. The receiver of this award ought to have a committed interest and should take activity in researching the later patterns and advancements towards the related subjects. You'll designate meriting of the award through online.

### Professional Level:

The Award for professional or scholastic research action procured in Plant Science research field within the public or private segment for specialists having research knowledge at 10+ years within the field of Plant Science with most relevant achievements. Part-time investigate experience would be tallied as pro-rata. It is calculated starting from the date after you obtained the first degree entitling you to set out on a doctorate (either within the nation in which the degree was obtained or within the nation in which the analyst is enrolled), indeed in the event that a doctorate was never begun or conceived. You'll designate meriting of the grant through online.

### Scholar Level:

The conference offers Researcher Level Award for the up and coming researchers, analysts and experts having 10+ a long time research experience in the field of Plant Science. Our conference would like to provide best stage to extend your organize by sharing your investigate information at stage. Presentation includes 25-30 minutes of oral talk on the scientific research topics based on the theme of the conference along with 5 minutes panel talks. You'll nominate deserving of the award through online

### Women Scientist:

Our Conference gives a special platform for women researchers for showing most recent research ventures with an in-depth analysis. We cordially invite women researchers and scientists from Universities/ Industries to who have 10+ a long time of research experience to connect the forum. We are happy to encourage our women scientist's members through research awards and give assistance for women researchers in career improvement and inquire about direction through our collaborations. Women Scientist can nominate deserving of the award through online.

### Outstanding Speaker:

This award is recognizing for person who will show their projects, strategies, and schemes that have been executed to move forward long-term excellence in Plant Science. You'll nominate deserving of the award through online.

### Best Keynote Speaker :

This award is recognizes for best Keynote speaker who will display their projects, strategies, and schemes that have been executed to improve long-term excellence in Plant Science. if you were confirmed as keynote presenter from the program manager, you can nominate somebody meriting of the award through online.

### Best Poster Presentation:

Student Poster Competition is organized at Conference, to energize students and recent graduates to show their unique research. All acknowledged abstracts will be displayed at the poster sessions during the conference. Conference Series points at setting a platform for all the budding researchers and analysts to display their real-time work and share their views and angles related to the subject of the conference. You can nominate somebody deserving of the award through online.

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