

Implantable Cardio Defibrillators and the Impact of a Shock to the Patient when Deployed

Research White Paper

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Preface

Introduction

FMCSA Medical Programs Division has a requirement for assistance in support of its efforts to understand the impact of Implantable Cardio Defibrillators (ICD) when they deliver a shock due to a cardiac arrhythmia. ICDs are small battery-powered electronic devices that are placed in the chest or abdomen of individuals at risk of sudden cardiac arrest due to arrhythmias. The ICD delivers an electronic pulse when it detects certain types of arrhythmias. Anecdotal evidence suggests that the deployment of an ICD may cause pain and/or incapacity at the time of, or for some period of time following, the shock to the heart. FMCSA is particularly interested in gathering evidence regarding the potential impact of ICD deployment; particularly those impacts that might interfere with the safe operation of a Commercial Motor Vehicle (CMV).

This report addresses the following questions:

- 1. The impact of shock delivery on the patient in terms of syncope and pain: Does the deployment of an ICD (shock delivery) cause syncope – a temporary loss of consciousness? What is the level of pain reported to be associated with the ICD shock delivery? Would this level of pain adversely impact the ability for a driver to safely operate a CMV?**
- 2. Following the delivery of a shock, is the patient able to continue normal activity, or does the shock cause a weakness, fatigue, confusion or other adverse side effects?**
- 3. Does an ICD deliver the same level of shock each time it deploys?**
- 4. If an ICD deploys, what is the risk or likelihood of its deploying again? In what timeframe?**
- 5. If an ICD is implanted but has been disabled by the medical provider, what medical fitness factors should be considered for the safe operation of a CMV?**
- 6. Under what conditions have ICDs been disabled by the treating medical providers?**

Report Organization

This report and systematic review contains three major sections:

- 1) Background information on ICDs
- 2) Methodology
- 3) Summary of Findings

The Background section briefly describes ICDs and their function, the medical conditions they treat, side effects of their use, and risk factors related to CMV drivers.

The Methodology section describes in detail the sources that were searched, as well as the search terms used for each research question and the overall evidence base.

Finally, the Summary of Findings provides a detailed description of the research results for each research question, including the input of subject matter experts (SMEs) consulted as a part of the research.

Report Funding and Role of Funders

This review was funded via contract DTMC75-13-R-00007 from the Federal Motor Carrier Safety Administration (FMCSA). FMCSA reviewed the report and provided comments. However, all research was conducted independently by Acclaro Research Solutions, Inc., and all findings are our own.

All authors declare no financial or other conflicts of interest.

Background

Implantable Cardio Defibrillators

Implantable Cardioverter Defibrillators (ICDs) are devices designed to detect and correct arrhythmia in the heart, preventing life-threatening cardiac arrest in patients with known cardiac disease. About the size of a pocket watch, an ICD is a battery-powered device that is implanted under the skin, typically below the collarbone. The ICD is connected to the heart via several small wires, allowing it to monitor the heart rate and, in the event an arrhythmia is detected, deploy an electric shock to restore a normal rhythm.

When the heart's normal electrical activity becomes disordered, unstable rhythms can occur in either the heart's atrial (upper) or ventricle (lower) chambers. ICDs are used to treat two types of arrhythmias occurring in the ventricles:

- Ventricular tachycardia (VT) – characterized by a heart rate over 100 beats per minute
- Ventricular fibrillation (VF) – characterized by a rapid and chaotic rhythm along with a loss of ability to pump blood

As of 2013, over 100,000 cardiac patients receive ICDs annually (Hohnloser & Israel, 2013). Since their development in the mid-1990s, ICDs have reduced overall mortality by 55% in patients who have the device implanted and reduced their risk of sudden cardiac death (SCD) to 1%.

How ICDs Work

The procedure to install an ICD device is relatively minimal, taking approximately 2-3 hours and requiring only local anesthesia. Weighing only about 70g, an ICD consists of a battery pack and a set of leads, or electrodes, which follow the veins into one or both ventricle chambers of the heart. Once implanted, these electrodes work continuously to monitor and wirelessly transmit intracardiac electrograms—information about electrical activity in the heart. In this way, an electrophysiologist is constantly able to access patient updates in order to adjust treatment plans and ensure the appropriate ICD responses (Young, 2012). If the patient experiences a life-threatening arrhythmia, the ICD device administers treatment in the form of electric shock.

ICDs differ from other common implantable cardiac devices such as artificial pacemakers or cardioversion devices. Whereas both devices monitor the heart rate and work to correct recurring arrhythmias, artificial pacemakers focus on the atrial

chambers of the heart, replacing the heart's natural pacemaker. When an arrhythmia is detected, a pacemaker responds with a series of low-voltage electrical impulses to the heart at a fast rate. A cardioversion device is similar in that it also transmits a low voltage electrical shock, but only one or two rather than a series of many. ICDs also function to stabilize heart rhythm, but due to the high voltage of the defibrillation shocks, the patient may be more likely to experience physical effects after the device response.

Types of ICDs

Original models of ICDs approved by the FDA in 1985 were relatively bulky and heavy, requiring implantation in the abdominal area. The procedure required extensive surgery involving a thoracotomy, and technological limitations did not allow for patient-specific programming. Data shows that abdominal ICDs frequently produced high rates of inappropriate shocks—anywhere from 25-40% (Gollob & Seger, 2001). Inappropriate shocks, also called inappropriate therapy, are incidents in which the ICD delivers a shock unrelated to a detected arrhythmia.

Development of smaller leads and battery packs allowed for ICDs to be placed under the skin in the pectoral region rather than in the abdomen. Transvenous pectoral ICDs allowed for implantation via a simplified procedure, as well as a significant reduction in recovery time. Pectoral ICDs reduced perioperative mortality to less than 1%. Complications, such as infection, were reduced to less than 3%, and inappropriate shocks were experienced by less than 5% of patients (Gollob & Seger, 2001). However, transvenous leads are prone to fracturing or breakage, which can lead to painful inappropriate shocks. Fractured leads also require removal and replacement, which is a difficult and risky procedure.

Less invasive subcutaneous models of ICDs (S-ICDs) are increasingly replacing transvenous models, providing the patient with 13% less chance of inappropriate shock. The S-ICD is reported to be less invasive, requires less time for implantation, and provides a treatment option for patients who may not have adequate venous access. Because it is located outside of the heart, the S-ICD is not exposed to the constant motion of a heartbeat, resulting in less cardiac stress than transvenous leads and contributing to the longer life of the device. The subcutaneous model also eliminates the need for thoracotomy upon implantation, which in itself had a mortality rate of 3-5%. More effective pacing methods allow for more efficient battery usage, leading to increased life span of the device (Gerstenfeld, 2013).

S-ICDs provide increased safety and ease while effectively terminating VT or VF arrhythmias when needed. S-ICDs are used for patients with no venous access, patients

who are at a high risk of infection, or patients who have experienced previous device malfunctions with a transvenous or abdominal ICD. Subcutaneous ICDs are beneficial for pediatric patients, women, and patients who show no evidence of monomorphic ventricular tachycardia (MVT).

Many recent model ICDs are dual function, and also operate as a pacemaker.

Whom are ICDs for?

ICDs are reserved for those patients with life threatening cardiac symptoms that cannot be safely regulated by prescriptions, cardio revascularization, or lifestyle changes. In the Antiarrhythmics Versus Implantable Defibrillator Trial, one of three secondary prevention ICD trials conducted in the 1980s and 1990s, qualifying patients were assigned to either receive ICD treatment or to continue receiving a variety of antiarrhythmics. The study was terminated early after results showed significant benefit to ICD treatment (Gollob & Seger, 2001). The Multicenter Automatic Defibrillator Implantation trial (MADIT), a primary prevention trial, demonstrated a risk reduction of 59% in patients who received ICDs compared to those who continued to solely receive pharmaceutical treatment (Hohnloser & Israel, 2013).

In order to be a candidate for an ICD device, the patient must exhibit symptoms that qualify for at least Class III of the New York Heart Association (NYHA) Classification of heart failure. Class III patients experience significant limitations to daily lifestyle. This could be shortness of breath while walking or performing basic movements (e.g., climbing stairs). Symptoms of a class III patient are likely to obstruct even minimal activity, and the patient only experiences comfort when at rest. Class IV patients exhibit severe limitations and constantly experience symptoms. Class IV patients are considered the most severe of the NYHA Classification, and are likely to be confined to permanent rest (American Heart Association, 2014). The tables below provide examples of conditions and medical test results which would indicate the need for an ICD treatment.

Table 1: The New York Heart Association classifications of heart failure

Class	Comfort at rest?	Limitations on activity?
I	Yes	None
II	Yes	Slight
III	Yes	Significant
IV	May have heart failure or symptoms at rest	Severe

Table 2: Medical conditions that may require use of an ICD

Condition	Definition
Ventricular Tachycardia (VT)	Abnormal electrical signals interfere with natural heart rate, causing it to become too fast. The heart is unable to fill with blood before contracting, which prevents enough blood from pumping throughout the body. VT causes dizziness, unconsciousness and in some cases, cardiac arrest (American Heart Association, 2014).
Ventricular Fibrillation (VF or V-Fib)	Abnormal electrical signals interfere with the natural heart rate, causing the ventricle chambers to 'fibrillate' rather than contract and expand. The heart fails to pump blood, causing cardiac arrest. VF leads to loss of responsiveness, abnormal or no breathing, and sudden cardiac arrest (American Heart Association, 2014).
Asystole	The absence of electrical activity in the heart means the heart is unable to beat (American Heart Association, 2014).
Cardiac Arrest (CA)	Malfunction of the electrical system in the heart causes the heart to abruptly cease function (American Heart Association, 2014).
Coronary Heart Disease (CHD)	Plaque that builds up in the arteries of the heart cause blood flow to be limited, causing damage to the heart muscle. The continuation of buildup can possibly lead to a heart attack (American Heart Association, 2014).
Acute Myocardial Infarction (MI)	Also known as a heart attack, MI occurs once the accumulation of plaque in the arteries has damaged the heart muscle enough to kill the tissue. MI may lead to cardiac arrest (American Heart Association, 2014).
Brugada Syndrome	Only detectable by an electrocardiogram (ECG), Brugada syndrome is a disorder which puts patients at much higher risk for arrhythmias and VF. Often inherited genetically, the syndrome is difficult to detect and shows few symptoms (Mayo Clinic, 2014).
Congenital Heart Defect	Abnormal development of the heart before birth results in a heart muscle that fails to operate. In many cases malformations affect the blood flow throughout the heart, causing cardiac arrest (American Heart Association, 2014).
Long QT Syndrome (LQTS)	LQTS is a hereditary condition that can only be detected through ECG. The peaks and valleys of the waves of an ECG are represented by the letters Q, R, S and T. A patient with LQTS experiences an abnormally long period of time between movements of the ventricles—from Q to S. Although these movements occur over fractions of a second, LQTS may lead to arrhythmias and cardiac arrest (American Heart Association, 2014).

Table 3: Medical tests that may indicate the need for an ICD

Measurement Method	Definition
Ejection Fraction	The left ventricle ejection fraction (LVEF) is a measurement of the percent of blood pumped through the left ventricle during each cardiac cycle. Physicians maintain that 55% is the normal rate. 35% LVEF signifies concern for the heart's ability to provide enough blood to the patient's body.
Electrocardiogram (ECG or EKG)	Detects and records heart activity over a few seconds, specifically how fast the heart is beating. The EKG also records the strength and timing of electrical signals. The data is symbolized by waves, the peaks and valleys of which are labeled as Q-R-S-T. Typically, a patient with a QRS greater than 120ms will be considered for an ICD.
Echocardiography (Echo)	Echocardiograms use high-frequency sound waves to record images of a patient's heart. The test will create a picture of the heart's structure: valves, chambers, walls and blood vessels.
Transesophageal Echocardiogram (TEE)	Similar to an echocardiogram, the TEE uses ultrasound imaging to record information about the structure of a patient's heart. Because a TEE uses a tube which passes through the esophagus to get closer to the heart, it is able to produce more detailed images than a standard Echo. A TEE provides doctors with information about the thickness of heart walls, how well the heart is pumping, and the flow of blood throughout the heart valves.
Holter Monitor	Device worn by a patient to record heart activity over the course of 24 or 48 hours. The Holter monitor provides doctors with information that cannot be recorded during the brief ECG.

Primary vs. Secondary Prevention

High rates of mortality due to sudden cardiac death (SCD)—approximately 350,000 per year in the United States—illustrate the need for identification and treatment of those individuals who are at high risk for SCD (Gollob & Seger, 2001). Primary intervention involves implanting ICDs in patients who have not experienced VT or VF, but show high risk of SCD. Patients may qualify for primary prevention if they show a history of at least four weeks of myocardial infarction (MI), exhibit left ventricle ejection fraction (LVEF) of under 30-35%, and show abnormal results during an echocardiogram (ECG) either in the form of QRS above 120ms or inducible Ventricular Tachycardia. A family history of cardiac conditions may also determine if primary prevention is necessary.

Secondary prevention involves implanting an ICD in a patient who has survived cardiac arrest which occurred as a result of VT or VF. Secondary prevention is also performed if a patient experiences sustained VT which results in syncope and produces LVEF of less than 35% (Hohnloser & Israel, 2013).

Contraindications

Studies show that patients with a single risk factor are actually at a relatively low risk of sudden cardiac death. However, this risk increases with the presence of more than one risk factor. Physicians generally agree that at least two signifiers of VT should be present before the ICD is installed (Buxton, 2005). On the other hand, studies show that patients who also exhibit conditions and factors relating to non-cardiac mortality will not benefit from the ICD device. For example, patients experiencing renal failure or chronic obstructive pulmonary disease (COPD) in addition to their cardiac risk factor will not benefit. Patients of an advanced age with a life expectancy of less than ten years will also not benefit. Less than 10% of ICD procedures occur in patients over the age of 80. In a recent study, "ICD therapy was not associated with reduced total or arrhythmic mortality in elderly (>70 years) patients ... ICD therapy in younger patients (<60 years) reduced all-cause mortality" (Hohnloser & Israel, 2013). Patients with terminal illness and a life expectancy of less than six months are not considered for ICD treatment (Gollob & Seger, 2001).

Patients who experience arrhythmia due to a reversible condition such as electrolyte imbalance, hypoxia, or sepsis are not candidates for ICD implantation. Similarly, for patients with VT due to a transient cause, such as electrocution, drowning, or a single myocardial infarction, undergoing an ICD procedure is not the appropriate course of action.

Impacts on Lifestyle

ICDs are used to extend the life of patients with certain cardiac conditions. ICDs may also improve the quality of life after implantation. Some ICD patients may be able to resume a near normal lifestyle. Yet, it is important to remember that the underlying condition still exists. ICD patients may be faced with limitations associated with the ICD itself as well as restrictions resulting from the underlying condition.

Psychological Impact

Patients who undergo an ICD procedure are at risk of both psychological and physical stress. ICD patients may experience anxiety, depression, or post-traumatic stress disorder (PTSD) as a result of device implantation or a near cardiac death. Subject matter experts also report that patients may experience PTSD or anxiety as a result of receiving a shock or in anticipation of the device deploying in the future. Psychological reaction to implantation, deployment, and the possibility of future ICD deployment vary widely and are a result of individual variability, with some patients experiencing significant symptoms and others reporting minimal or no concerns. The likelihood of psychological stress decreases over time, and is not uncommon soon after the procedure. The electrophysiologist is able to provide cardiac education and promote patient acceptance of the device. The patient may also benefit from interdisciplinary

support, in which case an electrophysiologist may refer the patient elsewhere for care (Sears, 2011).

Post-Implantation Restrictions

Following implantation, individuals with ICDs should limit their activities for a period of time, avoiding high-impact activities, heavy lifting, and/or anything that would cause pressure on the chest in the area where the device was implanted. Patients may still experience fainting and may not be able to return to driving until they have gone several months without fainting.

ICDs recipients should not engage in full-contact sports without permission from their physician.

Despite the restrictions described above, patients will be encouraged to maintain an appropriate level of activity.

Magnetic or Electromagnetic Devices

Electrical devices in the patient's environment can disrupt the electrical signaling of the ICD. Potential interactions include inappropriate shocks, inhibition of treatment programming, or a disturbance in the synchronization of programming. Odds of interference increase with frequency and length of contact. Because the patient is unlikely to notice this disruption, it is important that they practice caution around following items:

- **Electronic article surveillance systems/anti-theft systems** found in many retail establishments. The likelihood that one of these systems will disrupt the appropriate functioning of the ICD is minimal. As a precaution, ICD patients should avoid close contact and/or prolonged exposure to these systems (NIH, 2011).
- **Cell phones:** Although it is not necessary to entirely eliminate contact with cellular devices, it is recommended that a patient avoid placing a cell phone in close proximity to the ICD (e.g., in a pants pocket rather than the chest pocket of a shirt; NIH, 2011).
- **MP3 Players/Headphones:** Similar to a cell phone, the likelihood of interference from an MP3 is minimal. However, it is recommended that, should a patient choose to strap an MP3 player to their arm, they use the arm farthest from the ICD (NIH, 2011).
- **Household appliances (e.g., microwave ovens):** Regular day-to-day use of these items is unlikely to interfere with the ICD programming. However, it is not

recommended that a patient spend extended time near older models of appliances which may disrupt the device. Recent technological advances in both microwaves and ICDs decrease the likelihood of disruption, but the patient is always encouraged to practice caution.

- **Metal Detectors:** An ICD patient will be able to walk through metal detectors at a normal pace, as well as be screened by a hand-held detector wand if necessary. The patient should avoid standing or sitting for an extended time in the proximity of a security system metal detector. Physicians recommend alerting security personnel of the ICD (NIH, 2011).
- **Industrial Welders & Electrical Generators:** These machines have been known to rarely stimulate unnecessary shocks from the ICD. Again, increased proximity and time is proportionate to the risk. (NIH, 2011)
- **Citizen Broadcast (CB) or amateur “Ham” radios:** Similar to other small devices, CB radios should be kept at least 6-12 inches from the ICD site. Radios with larger wattage should be kept proportionally farther away. (AHA, 2014).
- **Medical Devices and Procedures:** An ICD patient should alert all medical officials of their device before undergoing MRI procedures. An electrophysiologist may provide a medical identification bracelet or card which explains details of the ICD. These should be presented to other doctors, dentists, etc. An electrophysiologist may temporarily deactivate the ICD therapy program in order to accommodate necessary procedures (NIH, 2011).

Medical procedures that may require deactivation of the ICD therapy program include:

- Magnetic Resonance Imaging (MRI)
- Therapeutic Radiation
- CT and CAT Scans
- Electrolysis
- Extracorporeal shock-wave lithotripsy (ESWL)
- Electrocauterization
- High-frequency, short-wave, or microwave diathermy
- Transcutaneous electrical nerve stimulation (TENS)
- Radio Frequency Ablation (RFA) or microwave ablation

Research Methodology

Research Questions

FMCSA has identified several research questions for this study. These questions are:

1. **The impact of shock delivery on the patient in terms of syncope and pain:**
Does the deployment of an ICD (shock delivery) cause syncope – a temporary loss of consciousness? What is the level of pain reported to be associated with the ICD shock delivery? Would this level of pain adversely impact the ability for a driver to safely operate a CMV?
2. **Following the delivery of a shock is the patient able to continue normal activity or does the shock cause a weakness, fatigue, confusion or other adverse side effects?**
3. **Does an ICD deliver the same level of shock each time it deploys?**
4. **If an ICD deploys what is the risk or likelihood of its deploying again? In what timeframe?**
5. **If an ICD is implanted but has been disabled by the medical provider, what medical fitness factors should be considered for safe operation of a CMV?**
6. **Under what conditions have ICDs been disabled by the treating medical providers?**

Sources Searched

Acclaro's team of researchers conducted a systematic search of thousands of peer-reviewed journals. The search strategy and the search terms were defined a priori. The following electronic databases were searched:

- **Academic Search Premier:** Full-text publications from all academic areas of study, including the sciences, social sciences, humanities, and medical sciences
- **The Cochrane Library:** A collection of six databases that contain high-quality information to inform healthcare decision-making
- **Cumulative Index to Nursing & Allied Health (CINAHL):** Over 700 journals on topics related to nursing and allied health

- **Embase (Excerpta Medica):** An index to pharmacological and biomedical literature from over 6,500 journals from 70 countries, including most MEDLINE records
- **Health Business Elite:** Articles in management, medical, general business, and industry-specific topics
- **National Guideline Clearinghouse (NGC):** Designed to provide physicians and other health professionals with an accessible mechanism for obtaining information on clinical practice
- **PubMed:** The National Library of Medicine's MEDLINE and PreMEDLINE databases; MEDLINE encompasses information from Index Medicus, Index to Dental Literature, and International Nursing Index, as well as other sources of coverage in the areas of allied health, biological and physical sciences, humanities, and information science as they relate to medicine and health care
- **Proquest Research Library:** Indexing, abstracting, and many full-text entries for over 2,800 scholarly and general-interest periodicals; covers a very broad range of topics and sources
- **Science Direct:** Web database for scientific research that contains abstracts, tables of contents, and full text of Elsevier journal articles mainly in science and medicine, with some coverage of social sciences and humanities, particularly business, economics, and psychology
- **TRID:** More than one million records related to worldwide transportation research

In addition, we searched the "grey literature," for relevant articles and content. "Grey literature" consists of unpublished reports, studies, and other materials which may not be available through academic databases. The following websites were searched:

- American College of Cardiology <http://www.cardiosmart.org/>
- American Heart Association <http://www.heart.org/>
- American Trucking Association <http://www.truckline.com/>
- Boston Scientific <http://www.bostonscientific.com/>
- Centers for Disease Control and Prevention <http://www.cdc.gov/>
- Clinical Trials <http://www.clinicaltrials.gov/>
- Commercial Vehicle Safety Alliance <http://www.cvsa.org/>
- Department of Transportation Bureau of Transportation Statistics <http://www.rita.dot.gov/>

- Federal Motor Carrier Safety Administration <http://fmcsa.dot.gov/>
- Food and Drug Administration <http://www.fda.gov/>
- Heart Rhythm Society <http://www.hrsonline.org/>
- National Institute of Health National Heart, Lung, and Blood Institute <http://www.nhlbi.nih.gov/>
- National Transportation Safety Board <http://www.nts.gov/>
- Transportation Research Board <http://www.trb.org/Main/Home.aspx>

Finally, we fully reviewed the references of retrieved articles in order to locate any additional relevant materials.

Search Terms Used

Relevant articles were searched using sets of specific keywords which were defined *a priori*. Combinations of search strings were used in order to maximize the number of articles identified and subsequently retrieved by researchers. All searches included “Implantable Cardioverter-Defibrillator” terms. The search terms utilized are presented in Table 4 below.

All searches were limited to the English language and to articles published on or after January 1, 2009. For databases where large numbers of results were returned (e.g., Science Direct) search terms were further limited to header/subject/keywords. Searching was completed in October 2014.

Table 4: Search Terms

Implantable Cardioverter-Defibrillator	("antitachycardia pacing" OR "cardiac pacing" OR "cardiac pacing -- methodology" OR "cardiovascular disease therapy" OR "defibrillation" OR "defibrillator(s)" OR "implantable defibrillator" OR "electric countershock" OR "electric countershock -- methodology" OR "implanted electrodes" OR "implant(ed) defibrillator shock" OR "implanted cardioverter-defibrillators" OR "shock")
Cardiovascular Status	("arrhythmia" OR "arrhythmia -- treatment" OR "atrial fibrillation" OR "atrial fibrillation -- prevention" OR "atrial fibrillation -- treatment" OR "automatic cardioversion" OR "cardiac arrest" OR "cardiac arrest -- prevention" OR "cardiac failure" OR "cardiovascular disease" OR "cardioversion" OR "heart" OR "heart arrest" OR "heart disease" OR "heart failure" OR "heart failure prevention and control")
Cognition	("cognition" OR "cognitive disorders" OR "cognitive impairment" OR "consciousness" OR "dizziness" OR "fainting" OR "impairing" OR "impairment" OR "implantable adverse effects" OR "lightheadedness" OR "loss of consciousness" OR "risk assessment" OR "syncope" OR "unconsciousness")
Driving, Commercial Drivers	("auto" OR "automobile" OR "driver" OR "driving" OR "motor vehicle" OR "commercial driving" OR "commercial motor vehicle" OR "commercial driver" OR "truck driver" OR "trucking")

Researchers reviewed the abstract for each article and, using the pre-defined retrieval criteria, and decided whether to retrieve it in full-text. Articles meeting the retrieval criteria were downloaded into a reference manager program (Zotero) for additional analyses. Some articles were identified in multiple sources and were not retrieved if they were already present in the reference program.

Once all databases and websites were searched, the selected full-text articles were reviewed for relevancy toward the specific research questions. The reviewer made a decision about whether each article should be included or excluded. In cases of uncertainty, the article was flagged for follow-up and reviewed by the Principle Investigator. Where articles were excluded, the reviewer also made a notation summarizing the reason for exclusion.

During the full-text review, researchers searched each article's reference section for additional relevant articles. Reference articles were retrieved and reviewed following the same procedures analyzed above.

After the final article review, 18 articles were identified. Of the eighteen total articles retrieved, ten of these articles were original research articles, and 8 were review articles and/or meta-analyses.

We also interviewed subject matter experts with in-depth knowledge of ICDs. We utilized their expertise to supplement the evidence available in the scientific and professional literature.

Summary of Findings

This section of the report presents findings for each research question. Each section first presents findings from relevant original research articles (n=37 across all questions) followed by relevant findings from literature reviews (n=11 across all questions) and where applicable, comments from SMEs consulted.

Research Question 1a

The impact of shock delivery on the patient in terms of syncope and pain: Does the deployment of an ICD (shock delivery) cause syncope – a temporary loss of consciousness?

Four articles were identified that address the occurrence of syncope due to ICD therapy. Results from these articles suggest that, though syncope occurs in some persons with implantable devices, it is inconclusive whether episodes of syncope observed in these four studies were the direct effect of ICD therapy, or if syncope was the result of an existing condition in these patients. Furthermore, Sorajja et al. (2009) reported that the type of syncope occurring most while driving is neurally-mediated syncope, a brief loss of consciousness brought on by a sudden decrease in blood pressure and heart rate, which is not attributed to ICD therapy, but rather a separate, pre-existing condition.

A retrospective study by Baning and Ng (2013) indicates that the incidence rate of syncopal episodes decreased over time following ICD implantation. However, Sarajja et al. (2009) found that of those patients who experienced syncope while driving (9.8%), almost half experienced additional syncopal episodes within 6 months of initial evaluation, and 70% experienced recurring episodes within 7 months of the initial evaluation. Although this study reveals the small likelihood of syncope occurring in ICD patients, the potential for recurring syncope episodes within those patients who do suffer syncopal episodes is significantly high.

Research Question 1b

**What is the level of pain reported to be associated with the ICD shock delivery?
Would this level of pain adversely impact the ability for a driver to safely operate a CMV?**

The question of the level of pain associated with the delivery of a shock from an ICD has not been thoroughly address in the scientific literature. Four articles were identified that addressed the impact of an ICD discharge on driving abilities. However, no articles were found which discussed the levels of pain associated with an ICD discharge. Subject matter experts who have treated patients with ICDs report that patients who have experienced a shock from the ICD frequently describe the pain as “like a blow to the chest” or “like getting kicked in the chest by a horse.” These SMEs also report that there is a great deal of variability in individual patients’ response to and description of the experience of receiving a shock.

A study conducted by Kawata et al. (2010) found the overall incidence rate, the occurrence of an ICD shock occurring within a year of surgery, in patients who have received an ICD replacement device to be 12.2%, a reduced rate compared to previous reports. Baning and Ng (2009) examined the risk of ICD discharge occurring while driving using three ICD studies and comparing the rate of discharge to the projected amount of time spent driving. Baning and Ng concluded that the highest risk for ICD shock was immediately following implantation, however, the likelihood of an event occurring was small at 1%, though the results of an accident caused by an ICD shock could be disastrous.

Williams and Treager (2009) conducted a systematic review and meta-analysis of the risk of ICD patients being involved in a motor vehicle accident. Researchers identified four relevant studies, of which one study found 11 patients to be involved in an accident over an eleven year period, however only one of these accidents was caused by the patient, and this was not shown to be related to the ICD. In addition, Zografos and Katritsis (2010) found that the risk of patients being involved in a motor vehicle accident is associated with the rate of inappropriate shocks, and that, if the rate of inappropriate shocks can be reduced, the risk of being involved in a motor vehicle accident may decrease as well. Furthermore, only one out of the seven patients included in this study were involved in a crash.

European driving guidelines for patients with ICDs assess the risk of harm associated with operating a motor vehicle. These guidelines refer to a generalized formula to calculate risk. The formula is presented below, where RH is Risk of Harm, TD is

proportion of time driving or distance traveled, V refers to the vehicle type, SCI is risk of sudden cardiac incapacitation for a given year, and AC refers to the probability that a SCI will result in an accident which will cause injuries or fatalities.

$$RH= (TD)*(V)*(SCI)*(AC)$$

Per the guidelines, the product of these variables should not to exceed 1%. The guidelines suggest that due to the time CMV drivers spend driving and the distance driven, as well as the severity of accidents associated with commercial motor vehicles, the risk of harm associated with the operation of a CMV is increased significantly. Therefore, the guidelines recommend that individuals with an ICD should not drive CMVs.

Research Question 2

Following the delivery of a shock, is the patient able to continue normal activity, or does the shock cause a weakness, fatigue, confusion or other adverse side effects?

Research has shown that 31% of patients will experience syncope or near syncope following an ICD shock (Thijssen et al., 2011). However, no research to date has investigated the occurrence of syncope or near syncope specifically related to inappropriate shocks.

Thijssen and colleagues (2011) assert that experiencing a shock from an ICD while driving would lead to severe detriments in driving abilities. Subject matter experts consulted in the conduct of this study agree, explaining that while some ICD patients experience less dramatic effects, treating physicians are unable to differentiate between patients who may have minimal reaction and patients who may have a more significant reaction. They also point out that the pain, weakness, fatigue, and confusion that is frequently observed is not the result of the shock itself, but rather the underlying medical condition. In some cases, the underlying medical condition causes a loss of consciousness prior to the delivery of the shock. In this event, the shock delivered from the ICD may revive the patient. The experience of syncope as a result of receiving an ICD shock is not clearly predictive of syncope in the event of a future shock.

It is also important to note that the underlying condition which prompted implantation of an ICD may carry the same level of risk of syncope as the ICD.

Research Question 3

Does an ICD deliver the same level of shock each time it deploys?

Current ICDs are programmable and the level of shock deployed can and generally is altered. Most often, if a series of shocks is required, subsequent shocks are progressively stronger. Before delivering a shock, an ICD will sometimes employ a pacing technique in order to correct an arrhythmia.

Subject matter experts report that low-level shocks may be used in the event that a patient's heart is so weak that a large shock would be destabilizing and could lead to worsening heart function; however, such a patient would likely not be in a condition to operate a motor vehicle.

A study was conducted in the early 1980s in which patients and doctors were blinded to the strength of two shocks. The study found that patients could not differentiate between shocks, and that the second shock always felt worse even if it was of a lower strength.

Research has also shown that once a shock is past 3 joules patients cannot differentiate between levels; for example, a patient would not be able to differentiate a 5 joule shock from a 30 joule shock.

Research Question 4

If an ICD deploys, what is the risk or likelihood of its deploying again? In what timeframe?

Much of the research published on this topic examines the issue of inappropriate shocks. We identified eleven articles related to this question. According to Lin et al. (2009), inappropriate shock is the most common device complication. Lin et al. found the rate of inappropriate ICD shocks to be significantly increased in some patients. However, the rate of inappropriate therapy can be reduced by methods such as updating algorithms in the implantable device.

Due to ethical concerns associated with altering the algorithm in an implanted device in patients with severe health issues, Volosin et al. (2011) used computational modeling to investigate the reduction of inappropriate shocks by altering the algorithm. Results from this study indicated that the overall rate of inappropriate shocks could potentially

be reduced by 59% by creating a more conservative formula of assessing whether or not a shock should be deployed by the ICD.

Furthermore, the application of this algorithm was applied to a large data sample of previously recorded electrogram events. Volosin et al. (2011) observed a 33% reduction of inappropriate shocks compared to previously used algorithms within one year following device implantation, where 3.6% of patients previously received inappropriate shock compared to 2.4% for the new algorithm.

In addition, Moss et al. (2012) were able to reduce the amount of shocks received by ICD patients by altering the device's algorithm. By creating a more conservative algorithm, the device was able to discriminate between events such as supraventricular tachyarrhythmias more efficiently and exhibited fewer device complications overall.

Gao and Sapp (2013) reviewed research related to the occurrence of electrical storms, which they define as receiving three or more ICD shocks in 24 hours. The likelihood of a patient receiving ICD shock within two years of implantation is high, 50-70%, and 10-20% of these patients will experience an electrical storm. However, the risk of an electrical storm is lower in patients who are receiving an ICD for primary prevention, 4% over almost two years.

Four of the eleven articles (Lin et al. 2009, O'Mahony et al.; 2012, Schinkel et al, 2012; Vriesendorp et al., 2013) assessed the rate of appropriate and inappropriate shocks. One of the four relevant studies (Vriesendorp et al) found a higher rate of appropriate therapy, 6.8%, compared to inappropriate therapy, 3.7%. However, the three remaining studies (Lin et al., 2009; O'Mahony et al., 2012; Schinkel et al., 2012) found a higher likelihood of an ICD patient receiving inappropriate shock compared to the likelihood of a patient receiving appropriate shock. The reported rates of inappropriate shock range from 4.6% to 5.1%, whereas the rates of appropriate shock range from 2.3% to 3.3%. Furthermore, patients who receive ICD therapy are at an increased risk for receiving additional shocks; however, it is unknown whether the rate of subsequent shocks differs between patients who first received appropriate or inappropriate shock. Furthermore, in a large scale study, Van Rees et al. (2013) found inappropriate shocks to be common among ICD patients, and mortality rates in patients were associated with the rate of inappropriate shock.

Thijssen et al. (2011) conducted a large cohort study to investigate the occurrence of appropriate and inappropriate shock, as well as the time from the first shock to the second. For primary prevention patients who averaged a follow-up time beginning at implantation of 784 days, 10% of patients received appropriate therapy and 34% of

these patients received a second shock with a mean time from first therapy to second therapy of 66 days. Ten percent of patients also received inappropriate therapy and of these, 27% received a second shock before follow-up with the mean time from first to second shock 224 days.

However, for secondary prevention patients averaging a follow-up of 1,442 days, 32% received appropriate ICD shock and 49% of these patients also received a second shock during this study with a mean time from first to second shock 400 days. Inappropriate shocks occurred in 17% of patients and 34% of these patients received a second ICD shock with a mean time of 243 days from first to second shock.

Research Question 5

If an ICD is implanted but has been disabled by the medical provider, what medical fitness factors should be considered for safe operation of a CMV?

Once implanted, ICDs are seldom disabled. Only one article was identified that addressed the event of an ICD being disabled. Vijgen et al. (2009) warn that the ICD itself is not the main cause for concern regarding driving; the underlying condition poses the greatest risk. These health conditions may cause events such as syncopal arrhythmias, which are a threat to safe driving.

Subject matter experts point out that if the ICD has been disabled due to recovery of LV function, exclusion from certification would depend on conditions other than the ICD. For example, if the LVEF remains 30% but the ICD is off, a determination to not certify a patient is based not the presence of the ICD, but rather a continued poor LVEF or other health problem.

Research Question 6

Under what conditions have ICDs been disabled by the treating medical providers?

ICDs are rarely disabled and this issue has not been addressed in the scientific literature. However, our subject matter experts reported that there are few conditions in which an ICD would be disabled by a medical provider.

ICDs can be disabled for a short term to repair damaged or fractured leads, to allow for completion of medical test or procedures, or in the event that a patient is receiving inappropriate shocks. Once the device is repaired or the procedure completed, the ICD would be reactivated.

It is rare for a patient to demonstrate an improvement in heart function significant enough that they would no longer require an ICD, and in this case it would typically be removed rather than disabled.

Finally, an ICD may be disabled due to terminal illness; however, in that event a patient would likely not be able to operate a motor vehicle.

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Appendixes

A. Subject Matter Experts

The following subject matter experts contributed to our research findings:

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