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Challenges and Solutions Facing EMS in Supporting the IOM Recommendation for a National Cardiac Arrest Registry: A System Perspective

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Challenges and Solutions Facing EMS in Supporting the IOM[1] Recommendation for a National

Cardiac Arrest Registry: A System Perspective

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[1] March 15, 2016 the Institute of Medicine was renamed The Health and Medicine Division.

Abstract

This white paper focuses on the feasibility of the Institute of Medicine's (IOM) recommendation to support a national cardiac arrest registry. A functional national cardiac arrest registry provides necessary research data to EMS and hospitals for improving cardiac arrest survival rates. This white paper contends the IOM recommendation falls short in considering the issues needed to ensure the success of a national cardiac arrest registry. Challenges facing the successful implementation of a national cardiac arrest registry are framed within systems theory because a) this is the theoretical premise underlying the IOM recommendation, and b) using a systems framework leads to explicit strategy recommendations for addressing the challenges. The challenges noted include a) a lack of shared understanding of the purpose of the national cardiac care registry between the research leadership at the national level and the EMS leadership at the state and local levels, and b) cascading failures caused by unrealistic expectations placed on participating local and state EMS subsystems in trying to support a national research agenda. These challenges bring into serious question the validity of any statistical analysis using EMS/prehospital data. Arguments are augmented by using past evaluations of the Cardiac Arrest Registry for Survival (CARES) and the evaluation findings of six Midwest and Mountain West EMS systems. Using systems theory, several recommended strategies are forwarded which EMS services should consider before making substantive investments in supporting a national cardiac arrest registry.

Table of Contents

Glossary

CARES	The Cardiac Arrest Registry to Enhance Survival (CARES) is an out-of-hospital cardiac arrest registry collecting data from state-wide registries, communities, emergency medical services, and hospitals in more than thirty states across the nation (CARES, 2016a).
Cascading Failure	Cascading failure may arise due to the domino effect in a system of interconnected parts where a failure in one part of the system causes failures in the other system parts (Buzna, Helbing & Peters, 2008; Ericson, 2011; Parson, 1961).
Centers for Medicare and Medicaid Services (CMS)	The Centers for Medicare and Medicaid Services (CMS) manages the publicly funded healthcare programs Medicare, Medicaid, and the Children's Health Insurance Program. CMS is also tasked with strengthening and modernizing the American healthcare system and administers the Health Insurance Marketplace (CMS, 2016).
Common Cause	Common causes are causes identified after aggregating multiple events (Clapper & Crea, 2010).
Configurability	Configurability refers to the adaptation of a computer system or a program for a particular use (Merriam-Webster, 2016a).
Continuous Quality Improvement (CQI)	Continuous quality improvement (CQI) is a feedback mechanism (see below) whereby the system is constantly seeking changes so its performance can be improved. The premise of CQI is improvements can always be made.

Credible Feedback

Feedback is a process of introducing information into the system concerning the adequacy of the system, its operations and its output (Banathy, 1992). Credible feedback is information considered trustworthy by system actors for decision making.

Critical Access Hospital (CAH)

Critical Access Hospitals (CAH) are rural hospitals benefitting from Medicare cost-reimbursement and funding opportunities. Eligibility criteria include 25 or fewer acute care inpatient beds, more than 35 miles from another hospital, average length of stay of 96 hours or less for acute care patients, and 24/7 emergency care services (RHI HUB, 2016). CAHs can provide essential emergency care to patients in cardiac arrest through their emergency departments.

Downstream Dependency

A downstream dependency or relationship means that an activity at a given point has a significant effect later in time or in a distant space (Scherer, 1990).

Effectiveness Metric

An effectiveness metric helps determine whether the right activities are undertaken to achieve the desired results (Drucker, 2006). For example, effectiveness metrics for cardiac arrest could be survival rates.

Efficiency Metric

An efficiency metric assists in determining whether activities are carried out right, but does not tell anything about whether the right activities are undertaken (Drucker, 2006). For example, efficiency metrics for cardiac arrest could be response times.

Emergency Medical

Emergency medical services (EMS) provide prehospital care to

Services (EMS)   out-of-hospital cardiac arrest patients. EMS level of medical

care differs from basic life support, which may be restricted to

effective chest compressions and use of a bag-mask device, to

advanced life support comprising a set of interventions and

medication treatments intended to support airway, breathing

and circulation.

eNARSIS   eNARSIS is Nebraska's web-based, statewide data collection

system for emergency medical services (Nebraska e-NARSIS,

2016).

Feedback Mechanism   Feedback mechanisms enable analysis of information generated

about the adequacy of the output and the operations of the

system. This analysis is used for introducing modifications into

the system to accomplish adequate output and improved

systems operations (Banathy, 1992). In the cardiac care

response system a common term for feedback mechanism is

continuous quality improvement.

Get With The Guidelines-   The Get With The Guidelines–Resuscitation (GWTG - R)
Resuscitation (GWTG – R)   registry by the American Heart Association collects data on in-

hospital cardiac arrest events. The participating hospitals

receive feedback on their resuscitation practices and outcomes.

The data is also used to develop new evidence-based guidelines

(American Heart Association, 2014).

Institute of Medicine (IOM)   Institute of Medicine (IOM) is a nonprofit institution that provides analysis and advice on how to solve complex problems and inform public policy decisions related to medicine. IOM is a division of the National Academies of Sciences, Engineering and Medicine. On March 15, 2016 the division was renamed The Health and Medicine Division (National Academy of Sciences, 2016).

Nonmaleficence   Nonmaleficence is a principle of doing no harm or cause the least harm possible to reach a beneficial outcome (Morrison, 2009).

Process Flow Mapping (PFM)   Process flow mapping (PFM) is a method used to document processes. PFM defines the order of all activities or steps required to complete a process. The resulting map visually illustrates the process using standard symbols.

Reflex Arc   The reflex arc is a concept of system adaptation based on feedback. An organism's stimulus response is sped up in the reflex arc where the sensory neuron goes to the spinal cord, is interpreted, and returned via a motor neuron (Philips, 1971). This system adaptation results in an organism being able to react more quickly to stimuli.

Special Cause   Special causes are causes identified for exceptional events (Chen, Corr, & Durango-Cohen, 2014).

Standard Operating Procedures (SOPs)   Standard operating procedures (SOPs) details the established methods to follow for a particular type of operations or in certain situations (Merriam-Webster, 2016b).

Sufficiently Frequent Feedback	Feedback is a process of introducing information into the system concerning the adequacy of the system, its operations and its output (Banathy, 1992). It is important the feedback is sufficiently frequent as long delays make information less useful due to memory decay (Averell & Heathcote, 2011).
System	A system consists of parts, subsystems, relationships, feedback mechanisms, attributes, and inputs, which interact in the surrounding environment and work toward a common goal (Renger, 2015).
System Actors	System actors are individuals interacting with or operating within a system (Renger, 2015).
System Evaluation Theory (SET)	System evaluation theory (SET) is a guiding framework for evaluators to conduct evaluations of modern day systems. SET is founded in system theory and describes how proven system theory principles can be used when evaluating systems (Renger, 2015).
Systems Framework	A framework for a systems approach to emergency response care involves a management strategy that recognizes system thinking and employs system methods (Hanfling, Altevogt, Viswanathan, & Gostin, 2012).
System Thinking	System thinking can be defined as the process of thinking using system ideas (Checkland, 1999).

Timely Feedback   Feedback is a process of introducing information into the

system concerning the adequacy of the system, its operations

and its output (Banathy, 1992). Timely feedback is information

available when the system actors need it. In the cardiac care

response system where time is of essence this may be

immediately after the data are entered.

Upstream Dependency   An upstream dependency describes a relationship where an

activity is dependent upon the accomplishment of another

activity to begin or move forward (Bettigole, 2014).

Utstein Survival   To establish uniform reporting on out-of-hospital cardiac arrest

data, a major international meeting held in the Utstein Abbey

near Stavanger, Norway, developed criteria for how to report

cardiac arrest survival (Cummins et al., 1991). According to

the criteria, survival should be reported for witnessed cardiac

arrest due to presumed underlying heart disease with the initial

rhythm of ventricular fibrillation (Jacobs et al., 2004).

Challenges and Solutions Facing EMS in Supporting the IOM Recommendation for a National

Cardiac Arrest Registry: A System Perspective

On June 30, 2015, the Institute of Medicine (IOM) released a comprehensive report

listing six recommendations for improving cardiac arrest survival rates (IOM, 2015). The focus

of this paper is on the first of these recommendations, which is to "[e]stablish a national registry

of cardiac arrest in order to monitor performance in terms of both success and failure, identify

problems, and track progress" (IOM, 2015, p. x).

In the health sector the term 'registry' generally refers to a place where patient data is

kept for research and/or comparative study (Gemmen, Pashos & Blanchette, 2009; Gliklich,

Dreyer, & Leavy, 2014; Merriam-Webster, 2016c; National Institutes of Health, 2015).

Registries are important in gathering research evidence to inform best practices and guidelines

(American Heart Association, 2014; IOM, 2015; Gemmen, Pashos & Blanchette, 2009). One

reason for a <u>national</u> registry is the need to gather sample sizes necessary for establishing

statistical power and for external validity: necessary research criteria for making

recommendations with confidence[2] (Bowling & Ebrahim, 2005; Gujarati & Porter, 2009; King,

Keohane, & Verba, 1994).

A national <u>cardiac arrest</u> registry stores and organizes research data for variables thought

to effect cardiac arrest survival rates (e.g., whether the arrest was witnessed, patient

demographics, response, and transport times, high performance cardiopulmonary resuscitation

(CPR) and hospital discharge status). The intent of gathering these data is to acquire knowledge

to improve the cardiac system of care by informing best practices, such as changes to CPR and

hypothermia protocols (American Heart Association, 2015; University of Pennsylvania, 2016).

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[2] Confidence is usually expressed in terms of statistical significance.

Not only does a national cardiac arrest registry allow for evaluation and changes in best practice

management, if easily accessible, such a registry will allow the data entry user to be given

feedback to compare their current performance based on known best practices in medicine.

According to the IOM, data needed to improve survival rates for time-critical events is

being collected by approximately one fifth of EMS systems and several hundred hospitals (IOM,

2015). Out-of-Hospital Cardiac Arrest (OHCA) and In-Hospital Cardiac Arrest (IHCA) data is

collected at the national, state and local levels. For example, at a national level cardiac arrest and

myocardial infarction data is being collected by the Resuscitation Outcomes Consortium (ROC)

Epistry (Morrison et. al, 2008), the Cardiac Arrest Registry to Enhance Survival (CARES,

2016a), and the Get with the Guidelines - Resuscitation Patient Management Tool (GWTG-R,

2016). At a state level the Arizona Department of Health Services collects state-wide data on

OHCA as part of its Save Hearts in Arizona Registry and Education (SHARE) program

(Bobrow, Vadeboncoeur, Clark, & Chikani, 2008). Examples of local level data collection

includes the Milwaukee County EMS system that maintains a database of all patients receiving

care from EMS (IOM, 2015, p. 72; Milwaukee County Department of Health and Human

Services, 2014), and the Seattle Fire Department's city-wide, quality improvement registry of

EMS-treated OHCA (IOM, 2015, p.72; Neumar et al., 2011).

While these independent data collection efforts are critical to inform local and state EMS

needs, the IOM report notes "it is both logical and necessary to integrate current efforts into one

cohesive national surveillance system for continuous and systematic monitoring, reporting, and

analysis of cardiac arrest data" (IOM, 2015, p. 79). However, an integrated surveillance system

poses numerous challenges. First, a national registry must coordinate data collection across a

multitude of emergency response subsystems including 9-1-1 emergency dispatch centers, (law

enforcement), emergency medical services, and hospitals (critical access and tertiary facilities): a daunting logistical challenge.

Second, data collected by these subsystems must be transferred to the national registry. For example, within the EMS subsystem this typically happens in one of two ways; either the data is exported from a local/state EMS registry to the national registry using information technology transfer protocols or the data is transcribed from a subsystem registry and reentered into the national registry (Barron-Simpson, Elmi, & Valderrama, 2011). Both options are fraught with data quality assurance problems. Exporting data is complicated by a) the plethora of different nationwide database software programs and the different versions of similar software programs being used by the different subsystems, and b) the different ways data is collected (e.g., manual entry versus transmitted EKG). The lack of database interoperability causes concerns about data integrity during data export (Granillo, Renger, McPherson, Dalbey, & Foltysova, 2014; Granillo & Renger, 2016). For paper based EMS agencies data must be transcribed and double entered. This adds time, costs, and reduces data reliability (De Vaus, 2002).

Third, there is a national span of control problem (Bell, 1967). Technical support must be provided by the national registry leadership to ensure data being entered by contributing EMS subsystems meets research standards. Numerous national registry data quality staff are required to manage the numerous and diverse participating EMS subsystems. Ensuring there are a sufficient number of national registry staff consistently enforcing data collection protocols and monitoring data being uploaded is an ongoing continuity of operations challenge.

Finally, there are significant, often overlooked, ethical concerns caused by the need to satisfy a national research data collection agenda (Renger, 2014). The reality is data entry

responsibility is often added and/or assigned to EMS staff. EMS staff responsible for data entry

require training and release time, the costs of which are absorbed by the EMS and state agencies

(IOM, 2015). The release time needed for training, data collection, and data entry place

significant strains on finite EMS subsystem resources: resources otherwise used to support

initiatives to improve patient outcomes (e.g., purchase better medical equipment, support

continuing medical education). The largest existing cardiac arrest registry in the United States,

CARES, does not subsidize these costs; in fact it adds cost by charging for their services

(CARES, 2016b). Diverting resources needed for patient care to support a research agenda

raises serious ethical concerns (Forester-Miller & Davis, 1995).

These realities pose significant challenges for EMS and the national leadership to meet

the IOM's recommendation of integrating reliable and valid data into a single cohesive national

cardiac arrest registry. It is the authors' contention to find solutions to these challenges it is first

necessary to understand the theoretical premise underlying the IOM recommendation and then

frame the arguments within this theoretical framework. That is, simply listing the national

registry challenges, as above, is not constructive because it lacks context and guidance for

corrective actions. The challenges must be reframed within a theoretical context so they can be

understood and solutions forwarded. The IOM notes its recommendation for a national cardiac

arrest registry is grounded in a system-level framework, that is, the unifying framework and

chain of survival (IOM, 2015). Therefore, the purposes of this paper are to a) frame the

challenges facing EMS in supporting a national cardiac arrest registry using system theory

principles (Renger, 2015; Von Bertalanffy, 1968; Williams & Hummelbrunner, 2010), b)

highlight the consequences of these challenges to the national cardiac arrest registry data

integrity, c) provide evidence of these consequences based on our experience evaluating six

Midwest and Mountain West EMS data collection systems, and d) use systems theory to recommend strategies for addressing these challenges.

In the interest of transparency the authors' have substantial experience working with numerous state and national registries (e.g., EMS databases, cancer registries, and Get With The Guidelines (GWTG)). However, our experience with a national cardiac arrest registry is exclusively limited to CARES. Nonetheless, since CARES has the largest catchment of all existing cardiac arrest registries (IOM, 2015) and is the national cardiac arrest registry endorsed in the IOM report, it is reasonable to assume challenges observed with CARES are also those needing to be addressed for the success of any national cardiac care registry.

Using System Theory to Frame Challenges Facing EMS Support of a National Cardiac Arrest Registry

1. System Theory Principle: An Efficient and Effective System Requires All Parts Working Together Toward a Common Goal

A successful national cardiac care registry is one that produces reliable and valid data for research purposes. To meet this goal requires a shared understanding of, and commitment to, the data collection goal by all participating system and subsystem actors (Renger, 2015). The need for a common understanding is especially challenging because the IOM suggests the national cardiac arrest registry must "…empower states, local health departments, EMS systems, health care systems, and researchers to develop metrics, identify benchmarks, revise education and training materials, and implement best practices" (IOM, 2015, p. 8). The different perspectives of these systems actors is a potential impediment to a shared understanding and must be

addressed to ensure system efficiencies and effectiveness (Innes, 2004; Williams & Hummelbrunner, 2010). Without this shared understanding leadership buy-in is unlikely (Becker, Renger, McPherson, & Dalby, 2015).

The impetus for a national cardiac arrest registry is to gather research evidence to improve cardiac arrest survival rates. However, our evaluation of four Midwest and two Mountain West EMS systems found local and state actors do not necessarily share this understanding. Many EMS agency staff and state EMS directors could not identify a single specific research question being answered by the data they were asked to collect. Further, many EMS leaders and staff believed the purpose of the national registry was to assist in local continuous quality improvement (CQI), but did not know how the standardized data elements required by their state and/or the national registry assisted them in meeting this purpose (K. Reed & J. Reed, personal communication, August 10, 2015).

For rural EMS agencies, there is even a larger disconnect to the common purpose because researchers are likely to exclude rural EMS and hospital data because the sample sizes are too small, creating an inherent urban bias in any reported data. As a result, the research reports generated at a national level do not contain information germane to making system improvements in the rural setting.

Compounding the problem are some state officials who believe they are required to gather national data elements, when in fact no such mandate exists (T. Nehring, personal communication, August 10, 2015). EMS system actors who do not have a shared understanding of the purpose of a national cardiac arrest registry will not be committed to its success and/or not understand how best to align their resources to ensuring the common goal is achieved (Fullan, 2004; Hinds & Weisband, 2003).

It is reasonable to posit leadership and actors across the cardiac care response system, by virtue of their chosen profession, share the goal of wanting to improve cardiac arrest survival rates by improving their response and care. However, it is the authors' contention there is a fundamental difference between how researchers at the national system level and EMS practitioners proceed in meeting this goal. The former collects data to answer broadly applicable research questions, whereas the latter uses data at the event level to inform practice. This difference was succinctly described by Tom Nehring, Director of the North Dakota Division of Emergency Medical Systems as the difference between special cause and common cause analyses.

Common cause analysis is designed to gather data relevant to policies and standard operating procedures applicable to all subsystems. To meet this goal requires gathering standardized data from numerous cardiac arrest events so as to have sufficient statistical power and external validity (i.e., representative samples). It can often take months or years to gather the data needed before a recommendation can be made with a high degree of certainty. For example, several years of resuscitation research was required before recommendations changing the practice of administering CPR (e.g., importance of minimizing pauses to CPR) and investment in technologies derived from this research (e.g., mechanical CPR devices) (Olasveengen, Vik, Kuzovlev & Sunde, 2009).

From a research perspective, standardizing data collection is necessary to ensure multi-site data can be merged so as to conduct meaningful analyses. The EMS community has certainly been cognizant of the need for a uniform data standard. The National EMS Information System (NEMSIS, 2016a) is the end product of years of development and standard setting. Its database is now accepted and used by over 90% of states and territories (NEMSIS, 2016b). "The

NEMSIS Project is an effort to create a National EMS Database. The database will contain data from local and state agencies from across the nation. This effort will define EMS and pre-hospital care in a way never before imagined, improving patient care and EMS curriculum and defining a *standard* on with to measure care. Agencies across the nation will be able to share the key elements of their data nationally" (NEMSIS, 2016c).

The system challenge is not related to creating agreement about the importance of standardizing data collection, rather what standardized data elements should be included in the national cardiac arrest registry. The ability to reach an agreed upon data set is impeded by the different understanding of the registry purpose between the national and local/state EMS subsystems. For example, despite the effort by the EMS community to adopt a national data set standard to eliminate data quality issues, CARES has been clear with several of the authors they do not believe they need to adopt this data set standard. This leaves EMS subsystems contributing to CARES with two options. First, they can simply not participate or second, they can enter their data twice into different systems.

There is evidence from our evaluation, data elements selected for inclusion for CARES are of limited interest and value to the EMS subsystems responsible for gathering the information. For example, EMS services in states we evaluated were interested in assessing the impact of recent investments in a specific type of mechanical CPR device. CARES either does not offer this level of configurability to gather and analyze data deemed meaningful at the local level, or would charge significantly to offer this level of configurability.

The lack of configurability in the national registry incentivizes local EMS agencies, hospitals, and states to develop their own data collection systems. Local and state EMS agencies design their data collection systems to gather both the required CARES elements as well as their

own data needs. From a systems perspective wasteful redundancies are created. Local and state EMS subsystems then attempt to offset their database development costs by uploading common data elements from their local/state EMS registries to the national registry. However, there is considerable variation in the EMS subsystem database software vendors creating significant database interoperability issues. That is, databases are unable to communicate with each other. Unfortunately, the cost saving strategy is offset by the significant, and in the authors' opinion, unethical cost subsystem software vendors charge to merge data with the national cardiac arrest registry.

In contrast to common cause analysis, special cause analysis can result in an immediate corrective action based on a single event. CQI processes at a local level often operate using a special cause model. For example, if a local EMS agency discovers its paramedics did not use a medical device correctly during a single call, then immediate corrective actions are taken such as refresher training, discipline, and so forth (McPherson, Souvannasacd, Bjerke, Schlosser, & Renger, 2016).

In summary, both common cause and special cause approaches are designed to improve cardiac care practice, but differ in their approach to so doing. The dilemma is in meeting the common cause analysis research requirements; local needs are often sacrificed. Researchers seek large samples and often operate from a "just in case" perspective; gathering data on variables that might be useful for answering yet to be defined questions. The practice of collecting data for undefined questions can be considered unethical (Elliott & Stern, 1997); it adds significant system burdens, diverting resources otherwise used to "do good" for an undefined benefit. Nevertheless, the practice continues and negatively influences the local level EMS in terms of motivation and resources. Researchers should be deliberate in requesting data

that is of meaning to them; data needed to answer questions based on sound theory (Johnson & Turner, 2003). This happens at some level, for example in gathering data needed to calculate the Utstein survival rates, but the data elements being collected far exceed just those needed for this one purpose. The research questions need to be made clear to all subsystems so as to achieve a common understanding of the data collection goal. Finally, when research questions are generated top down, as they are with CARES, many important new questions generated from field experience are lost.

Equally as problematic is CARES' premise that participation from all states is needed, presumably to obtain necessary sample sizes to meet the research purpose. While it is true, for example, that EMS cardiac arrest data from many smaller rural states may be needed to gather sufficient sample sizes to answer questions germane to the rural context, it is befuddling how researchers controlling the national cardiac arrest registry have lost sight of the proven sampling strategies available in response to practical constraints of trying to gather population level data. Participation from a substantially smaller, representative subset of local and state subsystems would still allow researchers to draw generalizable conclusions. This would also reduce system waste by placing less burden on additional subsystems for collecting data that does not add substantially to the degree of confidence to which research questions are answered (Cohen, 1988; Von Bertalanffy, 1968; Williams & Hummelbrunner, 2010). Of course, the counterargument is large sample sizes will create smaller confidence intervals improving statistical power. However, it is argued here a balance needs to be struck between actuarial and clinical significance (Dawes, Faust, & Meehl, 1989).

2. System Theory Principle: Systems are Susceptible to Cascading Failures

The development of a national cardiac arrest registry represents an endpoint in a complicated

data collection system. As such, a national registry will have numerous upstream dependencies

directly impacting the quality and trustworthiness of the data. In 2011, the CDC released results

of a commissioned evaluation report of CARES (Barron-Simpson et al., 2011). The report noted

numerous challenges such as EMS and hospital system actor competence, training, and

subsystem database interoperability (Barron-Simpson et al., 2011). When viewed through a

systems lens, these factors may all be considered upstream dependencies contributing to

cascading failures (Ericson, 2011). That is, a problem early in the system is continually passed

down the system creating a domino effect.

While CARES leadership assured the first author some of these upstream dependencies

are being addressed, our evaluation found many issues remain unresolved in several of the

Midwest and Mountain West states. First, the reality is the national cardiac arrest registry

depends on EMS and hospital subsystems for data collection. However, "CARES participation

is voluntary, and EMS agencies and hospitals that contribute information are not compensated"

(IOM, 2015, p. 69). Furthermore, many EMS and hospital staff are assigned the responsibility

for entering CARES data (i.e., duties as otherwise assigned). The lack of financial compensation

coupled with additional time demands on already burdened staff predictably lowers the

motivation of EMS and hospital subsystem leadership and actors to meet the national data

collection agenda. This in turn effects the data quality reflected as incomplete and inaccurate

run/hospital records.

Second, a national cardiac registry depends on trained EMS and hospital subsystem

actors for data collection and data entry. High performing EMS services such as those in Seattle-

King County (2016) are characterized by low staff turnover and high case volume. These two

factors create the conditions necessary to train dedicated staff for high quality data collection and

entry and ensure they continually have opportunities to hone their capabilities. In contrast, most

rural subsystems are unable to consistently provide the dedicated staff required to ensure reliable

and valid data collection and entry into the national registry. Many rural EMS and critical access

hospitals are volunteer dependent, experience high turnover, and struggle financially (Freeman,

Slifkin & Patterson, 2009). These are all significant upstream dependencies also noted in the

CARES evaluation affecting the ability to provide trained staff to enter reliable and valid data.

Third, the cascading consequences of forced compliance must be considered. Our

evaluation found some EMS staff responsible for data collection feel pressured to provide all the

data elements required by their state EMS and/or national registry. Alarmingly, when faced with

missing information they admit to falsifying information to complete a record (Renger,

McPherson, Rogan, Souvannasacd, & Becker, 2014). Further, the requirement to provide data

needed by the national cardiac arrest registry by some states means EMS agencies must serve the

data needs of their local agency, the state, and the national registry (NEMSIS, 2016d). The

problem posed was perhaps best illuminated in the Bible: "No one can serve two masters. Either

you will hate the one and love the other, or you will be devoted to the one and despise the other"

(Matthew 6:24 King James New Testament version).

Fourth, as noted earlier, database system interoperability is a significant upstream

dependency. As more vendors and software platforms enter the cardiac arrest data management

market, database system interoperability issues are becoming more rampant and widespread

instead of being resolved. Adding to the problem are the significant recurring fees charged by

software vendors to upload local and state EMS data to the national registry. This is cost

prohibitive for many states and discourages them from participating. The IOM report notes how

this problem then cascades at the national level "…because participation [in registries] is

voluntary, EMS and hospital systems that are already engaged in quality improvement, or have

the resources to participate, are more likely to report cardiac arrest outcomes, thus introducing

potential selection bias" (IOM, 2015, p. 74).

3. System Theory Principle: System Feedback Mechanisms Must Provide Credible,

Timely, Sufficiently Frequent Feedback

Healthy systems continually monitor the environment and use feedback to make ongoing

corrective actions to optimize efficiency and effectiveness (Renger, 2015). Registries are one

example of a type of feedback mechanism used by the cardiac care system and subsystems.

Other examples include feedback from medical devices, such as CPR compression rates

calculated from EKGs (Tranberg et al., 2015).

For a registry to be effective it must provide the system actors who enter data with

credible, relevant, specific, timely, and sufficiently frequent feedback (Chen, Hailey, Wang &

Yu, 2014; Renger, 2015). If feedback does not meet these criteria, then systems operate

inefficiently and ineffectively (Renger, 2015).

A national cardiac arrest registry is challenged to meet several of the criteria necessary

for a healthy feedback mechanism. First, it struggles to provide EMS with timely feedback. Of

course, what constitutes timely is open to interpretation, but suffice to say with advances in

information technology, timely is best defined as when the user requires it, which may be

immediately after the data are entered. However, the national registry can often take months to

provide feedback. One reason for this is the goal is to gather large sample sizes, which takes

time and results in feedback delays. *In short, the research mandate of the national registry*

undermines its ability to provide timely feedback.

Second, the national cardiac arrest registry does not provide EMS subsystem actors with

information relevant for decision making. The IOM acknowledges this issue when it states:

Each community is unique—a small, rural community with volunteer

EMS providers and long transport times is very different than an urban

city with a well-equipped EMS system that is connected to major

academic medical centers. Even different hospitals in the same

community may have varying functions, staffing patterns, and capabilities.

Therefore, one protocol may not be optimal in all community and hospital

settings. (IOM, 2015, p. 390)

An illustration of this problem are EMS response time benchmarks. Response times of under 5-

10 minutes in urban areas are meaningless performance benchmarks for rural EMS services

whose service area can span thousands of square miles. For example the West River Ambulance

Services in North Dakota is responsible for covering 2,500 square miles (West River Health

Services, 2016).

A national registry is also challenged to provide EMS with credible feedback. The IOM

report notes:

CARES participation is voluntary, and EMS agencies and hospitals that

contribute information are not compensated. Therefore, participating sites

must be willing to invest the time and resources necessary for data entry,

progress review and evaluation, and implementation of changes based on

feedback. CARES outcome data are limited by potential selection bias, as

higher-performing EMS systems may be more likely to voluntarily report

outcomes. (IOM, 2015, p. 69)

Our evaluation in the six rural states evaluated substantiates this observation as many EMS

services are a) low volume, and b) rely on volunteers to assist in data collection (Mohr, 2003).

The low volume of cardiac arrest cases in rural states relative to urban states brings into question

the credibility and utility of the performance benchmarks provided by a national cardiac care

registry.

Consequences of System Failures

The consequences of these system failures are predictable: missing, unreliable, and

invalid data. Our own analysis of EMS databases in several rural states substantiates these

consequences. Missing data was a prevalent issue in 1,130 cardiac arrest responses collected

from 100 EMS agencies in two rural states from 2012 to 2015. For example, over 40% of cases

have various missing key data elements such as 911 time, dispatch time, en route time, time

departed scene, time arrived hospital and odometer readings. Among the time-stamped events,

time arrived hospital has the highest missing rate of 28.5%, followed by time departed scene of

26%. Further, a large portion of data are clearly out of range, or contaminated with

miscellaneous problems such as misplaced decimal points, mistakes in the sequence of time

(e.g., time of dispatch is after the time en-route), inconsistent recording of odometer and distance

traveled, and inconsistent format for date/time. As shown in Table 1, after filtering out

questionable records based on quality assurance and quality control (QA/QC) criteria, *only one*

third of the cardiac arrest events entered remained.

Table 1

Data Processing Procedure

			Percentage (%)		
Step	Quality Control Objective	Data	Remove	Remain
1	Cardiac arrest	1130	0	100
2	Remove missing or invalid time intervals	648	43	57
3	Remove missing or invalid distance and speed data	426	20	38
4	Remove statistical outliers (three standard deviations)	405	2	36

The effects of including incomplete and invalid data can be critical. Table 2 shows summary statistics generated for a few key cardiac arrest time intervals in minutes. Also displayed in Table 2, the average of the four-year raw data (i.e., as originally entered) is considerably higher than that of the data after obvious problems are removed. Moreover, the standard deviation of the original dataset is substantially larger (i.e., less precise) than the data remaining after removing obvious problems. If benchmarks are established using the less precise, as entered data, then the actual effectiveness of the improvements and interventions can be undervalued or underestimated.

Table 2

Comparison Between Means and Standard Deviations (2012-2015)

Time Interval (minute)	Description	Mean (Std. Dev)	
		Raw	Processed
Response	Duration from the time the responding unit is notified to the time the responding unit starts moving.	5.34 (53.38)	3.16 (2.42)
En Route to Scene	Duration from the time the responding unit starts moving to the time the responding unit arrives at scene.	6.88 (6.91)	6.25 (5.06)
On Scene	Duration from the time the responding unit arrives at scene to the time the responding unit departs from scene.	19.40 (17.76)	17.79 (11.78)
En Route to Hospital	Duration from the time the responding unit departs from scene to the time the patient arrives at receiving facility.	11.83 (13.96)	11.61 (10.31)
From Dispatch to Scene	Duration from the time the responding unit is notified to the time the responding unit arrives at scene.	12.22 (54.58)	9.41 (5.71)
Overall Response	Duration from the time the responding unit is notified to the time the patient arrives at receiving facility.	40.29 (24.77)	38.81 (18.45)
Total	Duration from the time the responding unit is notified to the time the responding unit is available for the next service call.	74.15 (71.86)	72.69 (34.65)

Figure 1 further illustrates the consequences to decision making if the data being entered are assumed to be reliable and valid. A noticeable contrast can be observed based on the comparison between the two datasets using the yearly change of average en route time to scene and time to hospital between 2012 and 2015. The dataset, with obvious problems removed, reveals substantial decrease for en route time to scene and time to hospital in 2015: both are all-time low during the four-year time period. The raw data fails to uncover this significant improvement. According to the more trustworthy data, en route time to hospital has been steadily decreasing. For en route time to scene, a similar decreasing trend can be observed except for 2014. On the other hand, the raw data shows the average en route time to hospital oscillates over the years; and the trend for en route time to scene fluctuates as well but an increase can be found when comparing 2012-2013 with 2014-2015.

The different trends projected by the two datasets lead to divergent conclusions. The wrong projection can obscure or even nullify crucial findings associated with an EMS enhancement that actually helps to reduce the en route time. The performance goals established based on contaminated data can be confusing, questionable and less relevant. Moreover, low precision in the measurement can weaken the ability to distinguish high performers from low performers, impeding the positive progression of the institutional advancements and continued quality improvements.
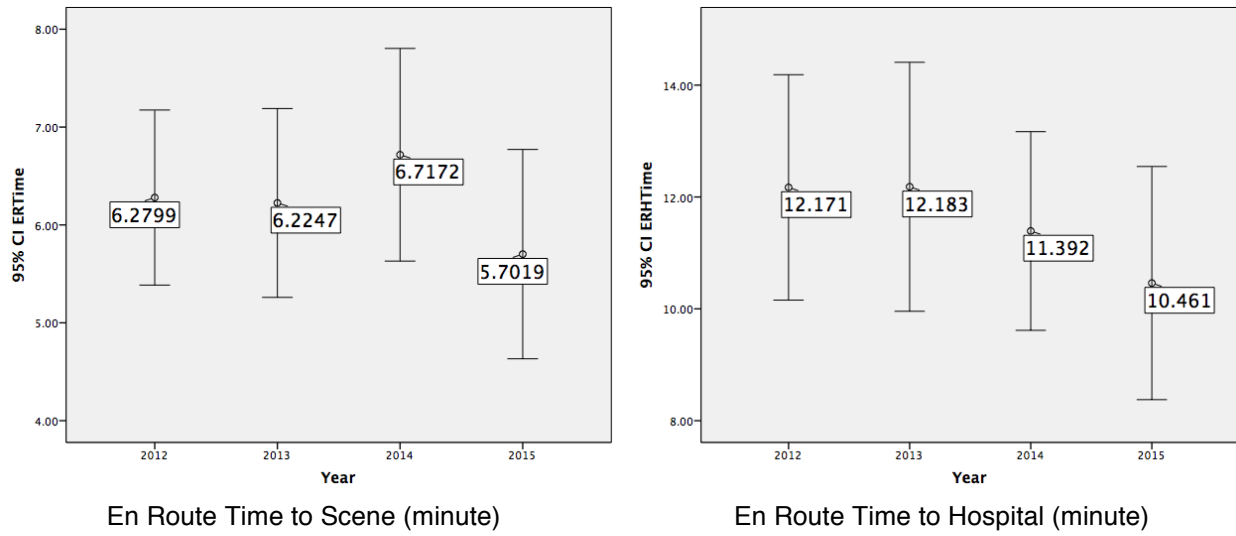
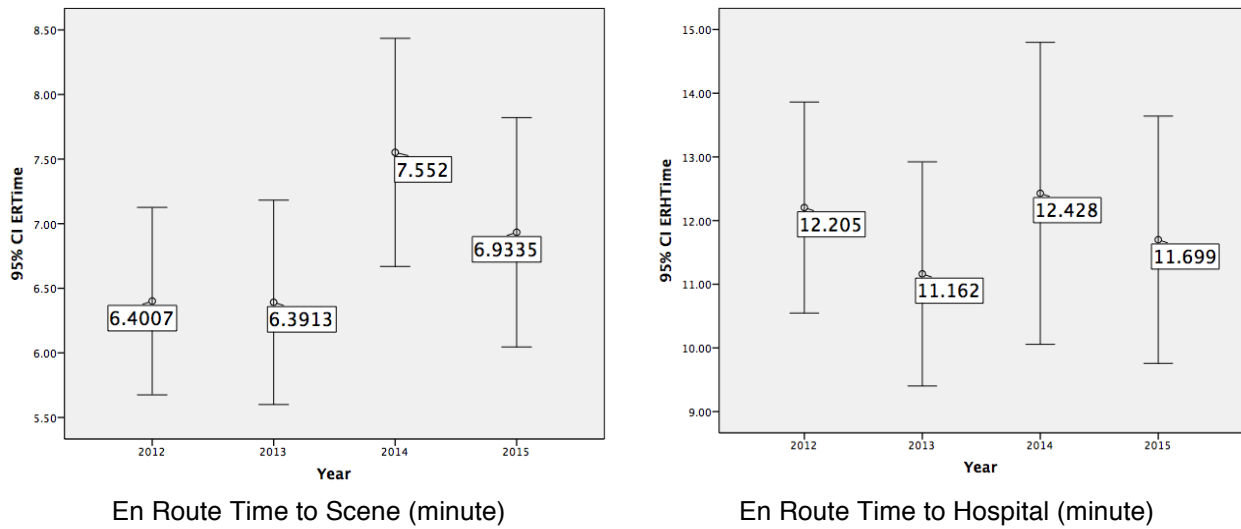*Figure 1a.* Yearly Trend of Time Intervals (processed dataset).

Figure 1b. Yearly Trend of Time Intervals (raw dataset).

High quality data is a precondition for addressing existing system deficiencies, establishing performance measures, informing decision-makers, and evaluating system success. These findings validate the concern regarding the data entry competence and/or motivation of the EMS subsystem actors. As noted above, alarmingly these data are passed to national data registry and therefore bring into serious question the validity of any resulting recommendations.

CARES' solution to ensure system accuracy is to use internal audits. What is not known would be the increased cost of the internal vetting of data if the registry moves in size from one of voluntary participation to one of mandatory national data collection. Further, no auditing system can detect inaccurate and falsified records falling within "acceptable parameters".

Using Systems Theory to Suggest Solutions to Overcome the Challenges Facing a National Cardiac Arrest Registry

It is clear some EMS system actors are not motivated to participate in data collection because of numerous upstream dependencies and lack of functional feedback mechanisms (Renger, 2015). Several recommendations and strategies targeting the three system challenges described above are now forwarded.

<ins>Recommendation 1</ins>: Ensure Leadership at all System Levels is Engaged in Understanding the Purpose of the National Cardiac Arrest Registry and Why It is Important

If the national researchers and local and state EMS leadership do not share a common understanding of the purpose of a national cardiac arrest registry, then strategies are needed to create this shared understanding. From a systems theory perspective system change requires the

coordination of at least four key system attributes: EMS leadership, culture of excellence,

information technology, and competent and capable EMS system actors (Eisenberg, 2013;

Renger, 2015). Arguably, the most important of these attributes is leadership. Leadership is

needed to create a common understanding, shape policies and leverage the resources to address

upstream dependencies.

Leadership is essential at all system and subsystem levels for the successful

implementation of any solution. The IOM report recognized the importance of this system

attribute when it stated:

Communities that have succeeded in improving survival clearly define the

people and entities that are responsible for the survival rates and often

identify a leader who is charged with overseeing and managing cardiac

arrest CQI efforts. This leader must have access to necessary resources in

order to identify and assess the gaps (e.g., less than optimal bystander

CPR rates, resuscitation protocols) and work with health care

professionals to improve outcomes. (IOM, 2015 p. 390)

State and local EMS leadership is needed to motivate national registry participation. The IOM

recommendation to make reporting mandatory (IOM, 2015, p. 85) is in the authors' view

punitive and counterproductive. Leadership must help subsystem actors understand *why*

participation in a national registry is of value (Mahoney, 2001; Owen, 2005). Initiatives like

EMS leadership academies that emphasize the importance of motivation need to be supported[3]

(Safe Tech Solutions, 2016). Leadership is especially important in motivating EMS subsystem

actors responsible for data collection when these duties are added to their job responsibilities

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[3] Contingent on demonstrating their impact via a stringent evaluation plan.

(i.e., for which they are not being compensated) and/or are volunteers. Understanding the "why"

is a necessary step to create a culture of excellence (Mahoney, 2001; Owen, 2005).

Recommendation 2: Increase Intrinsic Motivation to Participate in the National Registry

by Addressing Upstream Dependencies

   Strategy 1. Define data elements at the local (subsystem) level. To improve the

quality of data collection entry EMS subsystem actors must perceive the data elements to be of

value and utility (Patton, 2008). To do this a bottom-up, user driven model, as opposed to a top-

down, research driven approach to defining national cardiac arrest data elements is essential. A

bottom-up approach is supported by the Institute for Healthcare Improvement (IHI). In a report

on leadership and quality improvement (Kabcenell, Nolan, Martin, & Gill, 2010, p. 17), the IHI

noted within an organizational context, any potential change is more likely to be successful if it

is developed in collaboration with all levels of stakeholders.

   As currently designed, the national cardiac arrest registry data elements are selected to

serve the research, common cause agenda. Many elements are driven by the concerns of

NEMSIS, an EMS <u>research</u> registry (NEMSIS, 2016b). These data elements are then dictated;

there is no input from system leadership and actors. This in turn contributes to the system

leadership and actors' resistance and belief the national registry data elements do not reflect local

data needs.

   The importance of the *process* by which the national registry data elements are defined

cannot be overstated. It is very likely many of the data elements selected using a bottom up

approach will mirror the current national data elements (e.g., most time stamped variables,

bystander witnessed, etc.) because the key elements of an efficient and effective cardiac arrest

response are very similar regardless of demographics and geographic location. However, because the data elements are prescribed, there is resistance. Providing a list of recommended data elements for EMS subsystem leadership and actor consideration during their deliberations may achieve the dual goal of creating buy-in and collecting data deemed of value at the national level. Further, these data elements need to be routinely revisited to be sure they reflect local and state subsystem needs and to ensure continued participation in the registry.

In fairness, one challenge with the bottom-up approach is the number of data elements derived via this process is potentially infinite. This poses several immediate problems. First, as data elements to be included for data collection grow, navigating data entry software becomes unwieldy. In our evaluation numerous EMS subsystem actors complained about the challenges in navigating their own electronic patient care reporting (ePCR) and electronic medical record (eMR). Adding variables to a national registry to meet idiosyncratic subsystem data needs could inadvertently make it harder to enter these variables, thus decreasing motivation to participate.

Second, attempting to accommodate local EMS idiosyncrasies would add significant cost to sustaining the national registry. Cost in continually upgrading the national registry, updating and training users in changes, and creating feedback reports tailored to the new data elements would overwhelm the national registry resources.

Third, as the national registry moves away from standardized data elements to accommodate local EMS needs, the ability to benchmark across EMS services decreases. This problem was noted in the CARES evaluation report:

> One CARES administrator was unsure if he would recommend other EMS
>
> agencies to participate in CARES due to being unable to accurately

compare across agencies when different procedures are followed to

determine cardiac etiology. (Barron-Simpson et al., 2011, p. 11)

The key to a successful bottom-up approach is managing expectations of EMS subsystem

leadership and actors: it is simply impossible for a national registry to meet the data needs of

every subsystem. Methods are needed to honor subsystem input while maintaining a manageable

number of data elements in the national registry. Approaches used by initiatives like EMS

Compass show great promise in meeting this goal (EMS Compass, 2015a). EMS Compass

invited EMS stakeholders and the public to submit suggestions for performance measures

relevant to the EMS subsystem. Then, measures were selected based on relevance, usability,

availability of data, and the evidence base (EMS Compass, 2015b).

Researchers may argue using a bottom-up approach will result in some of the national

research agenda not being fulfilled (assuming of course that agenda is actually defined and

transparent). For example, some data elements may not have the necessary number of

observations needed for analysis. However, this must be weighed against the status quo which is

a) poor data quality bringing into question the reliability and validity of all conclusions, and b)

fewer EMS agencies participating because of the costs. Although larger sample sizes are

advantageous, advances in statistics can allow conclusions from small samples to be made with

similar degrees of confidence as those drawn from larger samples (Albert & Chib, 1993; Raftery,

1995). Therefore, the focus should be on ensuring the data can be trusted and limiting the

analyses to trusted sources. A conclusion based on a thousand trustworthy events is far better

than a conclusion based on ten thousand suspect events.

Strategy 2. Directly compensate local subsystems for participating in CARES. EMS

subsystems are not compensated for participation and as noted in the CARES evaluation report

this poses a significant burden to many EMS agencies, especially those in rural areas who are volunteer dependent. The CARES strategy to combat this is to highlight all the benefits of participation, many of which relate to the feedback available to participants. However, the reality is the feedback is often too slow (months), lacks meaning (data not useful for local CQI), and/or lacks relevance (benchmarks are biased to large agencies, with resources, and high case volumes) to participating local and state EMS agencies. The compensation model must be revamped. If the national registry requires the data and these data are important to the wellbeing of all taxpayers, then it should be a federally funded mandate. As currently designed, it is essentially an unfunded mandate.

Strategy 3. Remove punishment for not participating. The IOM recommends state and local health departments "[m]andate tracking and reporting of all cardiac arrest events." (IOM, 2015, p. 12). We question the wisdom of this recommendation because many of the rural EMS services in the states we evaluated are struggling to keep their doors open: they do not have the resources to comply. Adding this burden may a) be the proverbial straw that breaks the camel's back; forcing them to close, or b) encourage additional data fabrication/falsification.

Our evaluation supports other research suggesting instead of employing strategies to force participation, strategies designed to encourage intrinsic motivation work better (Deci, Koestner, & Ryan, 1999). For example, the North Dakota Department of Emergency Medical Systems is exploring a way of introducing friendly competition by showcasing a few of the high performing sites. The early results are promising.

Incentives need to be introduced to encourage prompt data entry. Rice and Campbell (2013) completed an exhaustive internal report to the EMS Board as well as the Governor's office looking at associations between good and poor quality of care. Random samples of

Advanced Life Support (ALS), Basic Life Support (BLS), paid, and volunteer services from all

Nebraska EMS regions were taken. Medical record data (eNARSIS in Nebraska) were reviewed

for completion, accuracy, and timeliness for completion. Medical records ($\underline{n}$=450) were then

hand audited by a physician and paramedic simply judging the quality of care. Relationships

between paid and volunteer; BLS provider and ALS provider showed no significant correlation

in care between ALS, BLS, volunteer, or paid provider. There were examples of small BLS

services which performed incredibly well and examples of ALS paid services lacking in the care

they provided. However, there was one single correlation with high quality of care the

researchers noted in Nebraska. The single identifying correlation was simply how quickly the

data was entered into the EMS data system. One could argue the quality of care may have been

present and just simply not recorded. However, from an evaluation perspective if it isn't written

down, it did not happen, it cannot be studied, and there is no proof it ever took place. A review

of 450 medical records showed consistently services completing their data reporting within 72

hours were likely to have no care issues or documentation issues greater than 90% of the time.

After 72 hours there was a linear degradation of quality in care and data reporting (including

accuracy).

In an attempt to address the problem of poor EMS data, Nebraska conducted major

overhauls of its rule and regulations pertaining to EMS. Two notable changes were the increase

in medical information to be supplied and the timeline in which it was to be supplied.

Strategy 4. Improve the quality of system feedback: Closing the feedback loop

more frequently with meaningful data. A common flaw of data collection systems are their

failure to provide timely feedback. In fact, many EMS data systems we evaluated do not provide

any feedback: system feedback loops remain open. This problem was also noted in the CARES

evaluation report which states "[o]ften, agency staff who are involved in the manual entry of CARES data elements do not see the hospital outcomes data, nor do the hospital nurses see the data elements collected from the ePCR." (Barron-Simpson et al., 2011, p.10). Closing system feedback loops by providing sufficiently frequent, understandable, and usable information to the local EMS subsystem user increases motivation to participate and is more likely to lead to remediation of the data quality problem (Renger, 2015).

While closing system feedback loops is critical, they must be closed with meaningful and timely data. The IOM concludes every hospital and EMS system treating cardiac arrest patients should be capable of analyzing its outcomes, protocols, training, and performance using CQI (IOM, 2015). Even though many EMS agencies and hospitals will not achieve the benchmarks set by high performing agencies, each health care agency and institution should be able to continuously work to improve its survival rates (IOM, 2015). *That is, agencies must first and foremost be able to benchmark against their own average previous performance.* However, the CARES system only allows "participating EMS agencies to access their own data and generate reports by date range, and to benchmark their performance against a summary national report" (IOM, 2015, p. 69). In its current form the feedback provided by CARES is inadequate in increasing local level motivation to participate.

To solve these issues the CARES evaluation report recommended enabling hospital staff and EMS staff to both access and customize local data (Barron-Simpson et al., 2011). To date the CARES leadership remains resistant to providing the configurability necessary to allow local level analyses and benchmarking (B. McNally, personal communication, January 21-23, 2015). It should be noted highly configurable state EMS cardiac arrest registries are available (Imagetrend, 2016). However, for many states the cost is prohibitive. Having a single, highly

configurable national registry would remove redundant state level systems resulting in significant system saving: one system instead of several would be needed.

Our evaluation suggests two key configurability parameters are necessary to increase motivation to participate in a national registry. First, as noted above local EMS subsystems must be able benchmark against their own previous performances. Our evaluation found local EMS agencies are intimidated by the comparisons to other EMS agencies and such a comparison can have the reverse effect: fostering feelings of inadequacy and decreasing motivation. Second, the ability to compare to other subsystems with similar demographics and volume is highly desired. That is, there is a preference for peer group comparison (Byrne et al., 2009).

Strategy 5. Ongoing EMS data entry training. Ongoing training is needed for EMS state and local system actors responsible for data collection. The training must be supported by state and local EMS leadership. The training should emphasize the why and the value of data collection in the quality improvement cycle.

A major barrier for many EMS services, especially those in rural areas, is their ability to maintain a trained EMS staff member responsible for data collection given a) they are volunteer dependent, b) the service may be experiencing high turnover, and c) the infrequent number of cardiac arrest calls to keep cardiac arrest data collection skills honed. When dealing with volunteers it is important to manage expectations during recruitment; specifying data collection and documentation as an important part of the job as well as the adrenaline rush of going on a call. In addressing issues "b" and "c" above one solution meeting with some success is designating a single high performing regional EMS agency the responsibility for entering data for numerous EMS agencies (K. Reed & J. Reed, personal communication, August 10, 2015). This strategy eliminates system redundancies, provides the EMS service responsible for data

entry with the cases needed to stay sharp, and generates a small remuneration to support the

EMS staff person responsible for data entry.

Recommendation 3: Reduce System Redundancies/Waste: Local Control of a Consolidated National Registry

      EMS strive to be efficient and one way of so doing is by eliminating waste by reducing unnecessary system redundancies. There are two possibilities for restructuring the EMS data collection system to eliminate system redundancies/waste.

      The first strategy is to eliminate local and state EMS data collection registries. While it is acknowledged states are often required by federal agencies to maintain databases, another reason why states maintain their own cardiac arrest data collection registries is the desire to maintain control over their own data. They require more timely and configurable data analyses than what is offered by CARES. To be true to the IOM recommendation that the cardiac arrest registry serve local and state EMS needs, then the national cardiac arrest registry must make investments to increase its configurability. It is predicted this would result in a significant system shifts toward efficiency. For example, there would be an exponential informational technology cost savings by removing the initial and recurring charges by the EMS database vendors; the proverbial middle men. That is, there would be a one-time configurability, web-based data entry, server, and security cost, which is opposed to the current model where the same cost is incurred by all participating states and agencies. Push-back from EMS vendors to this idea is expected as it effects their livelihood, however in the authors' opinion this should be viewed as a positive indicator of system change.

A second strategy for increasing efficiency and eliminating system waste, not mutually exclusive of the first option, is to move to a single time-critical event registry. This strategy builds on the aforementioned IOM note that "it is both logical and necessary to integrate current efforts into one cohesive national surveillance system for continuous and systematic monitoring, reporting, and analysis of cardiac arrest data" (IOM, 2015, p. 79). There is considerable overlap in data collected for time-critical events. For example, many EMS subsystems are required to collect data for many types of time-critical events (e.g., stroke, cardiac arrest, etc.). Often the same data elements are required regardless of event type (e.g., time to scene is a required data element for stroke and cardiac arrest). These same data elements must often be uploaded into separate event-based registries (e.g., CARES and GWTG). Defining the data elements consistently across all time-critical events would increase system efficiency and motivation to participate. This would reduce system waste by reducing training costs (i.e., only need to learn one set of core variables for all events) and reduce taxpayer cost for maintaining numerous systems.

One example of eliminating redundancies is occurring in Nebraska. Nebraska has begun working on a project called the Nebraska National Cardiovascular Disease Registry. Unlike the multiple national registries that silo separate elements of cardiac disease (e.g., CARES, Get with the Guidelines, Cath PCI), the design of the Nebraska National Cardiovascular Disease Registry would pool all cardiovascular elements. There would be multiple benefits from having a state or local agency execute a project of this nature. They include and are not limited to:

1. Price point for data is a fraction of having multiple national databases. The data is already paid for, exists, and there are no additional charges to submit information to a national organization.

2. Data design allows for immediate feedback to the beneficiaries of the data. Users can not only see immediate metric feedback of performance but can also ask their own scholarly questions which might not be the focus of a national organization like CARES or Mission Lifeline.

3. Those that contribute participate in the changes in national and local care guidelines. Data deemed invaluable at a national level may still have relative importance at a local level.

4. Data is not for the proprietary use of a select few. New centers of academic excellence can participate in the advancement of medicine without being constrained or limited by previous research and publications from small, exclusive organizations. This may be one of the best advantages of a local national database, the desegregation of costly national organizations and the emergence of more diverse medical thought and contribution to our understanding of cardiovascular disease.

5. States already collect this data. With less cost, data can be pooled allowing for more meaningful analysis factoring "urbanicity" of suburban and rural care that is often excluded from study simply due to the lack of numbers.

6. With the combination of cardiac center data, hospitals could retrieve data for their own benefits. One example would be to possibly identify Physician Quality Reporting System (PQRS) data points and submit them to the Centers for Medicare and Medicaid Services (CMS) for higher reimbursement. Similarly, other databases like the one proposed in Nebraska could actually result in higher reimbursement as well as doing it at a lower maintenance cost.

7. Nebraska's prehospital data is housed in a system that is currently used by 26 other states. This means with some collaborative work, a single state's grass roots effort could quickly grow into the single largest data repository for prehospital data. And unlike national organizations, a combined state's national cardiovascular disease registry would be readily available by every one of those states, their regional agencies, local agencies, and down to the single EMT who simply wants to research their own ideas.

8. From a data security standpoint it is significantly more costly to protect redundant data stored in multiple locations from a security breach, such as being hacked or being leaked, than to protect the same data stored in a single location.

Discussion

The IOM recommends supporting a national cardiac arrest registry. There is tremendous potential of a national registry to contribute to improving cardiac care. However, a real-world national cardiac arrest registry is the endpoint of an intricate, multifaceted, and complex system. From a system perspective the success of the cardiac arrest registry depends on many upstream factors, functional feedback, and support of system attributes such as leadership. The IOM states its recommendation is rooted in a systems framework. However, it is the authors' position the report falls short in using this framework to understand the constraints in supporting a viable national cardiac arrest registry.

Based on the independent CARES evaluation report and our own evaluation of the EMS cardiac care systems in several rural Mountain West and Midwest states there is a lack of common understanding regarding the purpose of the national cardiac arrest agenda among the stakeholders the registry is intended to serve (i.e., local health authorities, state health authorities,

EMS, hospitals, etc.). In the case where there are clear weaknesses in the data, the lack of

common understanding may be more obvious. However, it is not safe to assume there is a

common understanding simply because a subsystem is reporting required data correctly.

The current leadership responsible for the national cardiac arrest registry are research

focused and employ a top down approach to identify key data elements. Gathering the data

necessary to answer research questions can take several months, even years. The questions being

posed at the national level are not always of interest to those at the local and state EMS level

responsible for gathering the data. Local EMS actors are more interested in practical changes

they can implement to improve care. To add insult to injury EMS subsystems needed to support

the national agenda are required to pay to do so.

As a result of the national research focus, EMS subsystem leadership at the local and

state level feel disconnected and lack the resources to participate in motivation to participate.

This cascades into gathering incomplete and inaccurate data. No error checking protocols at the

national level can prevent missing data or detect fabricated/falsified data falling within

acceptable parameters.

One solution being sought by many states is to purchase new EMS data collection

software. Be warned! This will not solve any other data reliability and validity issues. From a

systems perspective it is clear a new EMS data collection registry itself is not the silver bullet.

Engaging EMS leadership to support system change, increasing intrinsic motivation to

participate by providing timely and credible feedback through highly configurable interfaces, and

removing unnecessary system redundancies are some of the strategies necessary to sustain a

viable cardiac arrest registry at any level.

Many of the system challenges facing a national cardiac arrest registry described above are based on an independent evaluation of CARES and our own observations while evaluating several rural EMS cardiac care systems. Additional research is needed to determine a) the pervasiveness of the EMS challenges affecting the trustworthiness of data we observed, and b) to identify regional EMS subsystems of high quality data collection and the conditions supporting this so it can guide best practices. For example, are other states facing EMS data collection, entry, storage, and transmission problems? To what extent do the problems observed in the EMS subsystems extend to hospital subsystems? For example, our preliminary discussions with critical access hospitals (i.e., possessing similar demographic characteristics as volunteer EMS services) suggests many of the factors affecting trustworthiness of data are operating at this subsystem level as well (e.g., emergency department data).

Researchers analyzing the national cardiac arrest registry data assume data protocols to ensure integrity are being followed; they assume the data is reliable and valid. They are not. Researchers have a responsibility to ensure the conclusions derived from their analyses are reliable and valid. Researchers are also system actors and as such are responsible for ensuring upstream issues leading to cascading failures in data integrity are addressed. Researchers must realize they are a part of the system, necessary for closing feedback loops with meaningful and timely data analyses. Their feedback loops are to state and local EMS agencies (downward) and to federal policy makers and regulators (upwards). Their failure to understand and see themselves as an integral part of the system contributes to the problems in obtaining the reliable and valid data they need.

In conclusion, not addressing the current system failures brings into serious question the credibility of any recommendations for improving cardiac care based on the national registry.

The solution to the problems with the national cardiac arrest registry cannot be resolved by amassing even more flawed data. Investing in a national registry without introducing strategies to resolving these system issues is flummadiddle.

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