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SAFE EMERGENCY TRANSPORT OF NEONATAL PATIENTS (SETONP) PROJECT PHASE I WHITE PAPER

NEONATAL TRANSPORT SYSTEMS SAFETY CONCEPTS

An interdisciplinary perspective bridging clinical focus with the engineering sciences of transportation and automotive safety, biomechanics, human factors and ergonomics

SETONP is a collaborative project
of the EMS Safety Foundation,
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Neonatal Transport Systems Safety Concepts

Neonatal patients are routinely transported to tertiary care facilities, not infrequently over long distances, via ambulance/critical care transport using a spectrum of transport approaches and with varying degrees of sophistication and attention to safety. The objective of this project is to optimally address the safe transport of neonatal patients from a systems approach and based on relevant interdisciplinary technical science, with awareness of the requirements of clinical care enroute.

There has been increasing focus on medical transport safety in the past decade. There are now recent medical transport safety publications such as CAMTS Safety and Quality in Medical Transport Systems – J Overton, E Frazer, and also a strong safety focus in the recent AAP Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients, 4th Edition. Safety science is interdisciplinary. The relevant interdisciplinary sciences bridge across the realms of engineering, transportation, human factors, ergonomics and acute medical care as they interface with safety. Specifically these sciences include systems engineering, biofidelic and biomechanical engineering, vehicular occupant protection, operational ergonomics, fleet management practice and transportation safety systems. Utilizing a comprehensive technical interdisciplinary team, what is addressed in this White Paper is an introduction to the important elements of these transportation and engineering sciences (including a glossary of technical terms), so as to facilitate their integration with an applied operational clinical perspective in the neonatal transport setting.

The SETONP team included a diverse interdisciplinary spectrum of expertise from university, engineering, operational and clinical settings under the umbrella of the independent EMS Safety Foundation. This expertise included technical experts in systems engineering, transportation science, child occupant protection, basic science, biomechanics, neonatal anthropometry and physical properties, human factors and ergonomics, emergency medical services, neonatal transport operational expertise and neonatal clinical care providers from North America, Europe, Scandinavia and Australia.

The task of this SETONP project is to address the interdisciplinary technical and scientific operational aspects of safety in neonatal transport. It is felt by the project team that given both the pressing need for sharing existing technically sound transportation safety information in this arena, and the knowledge of substantive current morbidity and mortality, that a basic White Paper such as this to share this technical interdisciplinary information is warranted, if not imperative. Such a guide for accessing what is known in the engineering and transportation fields and what directions need to be explored further is of great value to the field of neonatal transport.

The ultimate goal of the SETONP Project is to operationally impact the neonatal transport arena with interdisciplinary systems engineering technical data and design for optimal safety. This involves a process of integrating transportation safety engineering science, clinical task analysis, human factors, neonatal patient size and age appropriate anthropometry and biomechanical properties. Our future focus is on development and validation of a functional and operational model to identify optimal neonatal transport practice safety, and creation of more comprehensive educational material, including video, illustrating the concepts of operational safety embracing transportation and engineering science.

This Preliminary White Paper is based on established technical principles and existing published and pre-publication neonatal transport, automotive safety, biomechanical and ergonomic literature and data, to enhance the system safety of neonatal transport.

There are 8 aspects of neonatal transportation safety that this White Paper addresses. These follow the template of the National Academies Transportation Research Boards ANB10(5) 2012 EMS and Medical Transport Safety Subcommittee's Systems, Strategies and Solutions Summit.

Glossary:

- *Interdisciplinary* - involving two or more academic, scientific, or artistic areas of knowledge, crossing traditional boundaries between academic disciplines or schools of thought, as new needs and professions have emerged. Ie. Neonatology and occupant safety engineering
- *Systems engineering* - ensures that all likely aspects of a project or system are considered, and integrated into a whole. It overlaps technical and human-centered disciplines such as control engineering, industrial engineering, organizational studies, and project management and deals with work-processes, optimization methods, and risk management tools.
- *Biofidelic* - meaning they mimic pertinent human physical characteristics such as size, shape, mass, stiffness, impact tolerance and energy absorption
- *Biomechanics*- area of study where the knowledge and methods of mechanics are applied to the structure and function of the human or any living creature
- *Impact Biomechanics* - Biomechanics concerning the mechanical response and injury of the human body under crash or impact conditions
- *Biomechanical* – the interrelationship of mechanical measurement and human mechanics
- *Anthropometry* - the scientific study of the measurements and proportions of the human body
- *Occupant protection* – a combination of the science of vehicle safety engineering and human impact biomechanics
- *Ergonomics* - is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance.
- *Operational ergonomics* – an applied science of designing and arranging a work environment and equipment so that people can perform work tasks and use equipment easily and safely
- *Human factors*- is concerned with the application of what we know about people, their abilities, characteristics, and limitations to the design of equipment they use, environments in which they function, and jobs they perform
- *Invehicle telematics* - devices incorporating wireless communications technologies to provide fleet information on vehicle safety performance, tracking and diagnostics and other functions including real time feedback to drivers and management.
- *Fleet management* - includes a range of functions, such as vehicle selection and acquisition financing, vehicle maintenance, vehicle telematics, driver management, speed management, fuel management and health and safety management.
- *Crash worthiness* - ability of a vehicle to withstand a crash with minimal bodily injury to its occupants
- *Electronic Stability Control (ESC)* – an electronic system built into a vehicle by the original manufacturer, that substantially minimizes the potential for loss of control of the vehicle

1. **Exposure**

   Fewer than 10% of pediatric ambulance transports are for neonatal patients, some of these transports occur in 'specialized neonatal vehicles', others in regular or standard ambulance vehicles. Though current data suggests that neonatal medical transport has lower transportation related morbidity and mortality than general medical transports, there remains morbidity and mortality risk not just limited to the transported neonate but for patients, providers and the public. Much of the existing transport crash data is sample data, and may not have captured all injuries and fatalities, let alone morbidity and mortality from near miss crash events. There is no national system yet of oversight of adverse event in neonatal transport systems. Currently there are some promising initiatives to increase clinical data capture of safety performance – however, not yet data captured on systems safety performance overall nationally. Despite the identified vehicle and transportation hazards, most neonatal transport vehicles are designed by hospital and pre-hospital health care providers fundamentally with no training or background in vehicle design, occupant protection or transportation systems engineering. The existing state of the art in systems engineering, occupant protection and human factors applied design and technology is seldom integrated into the design and management of neonatal transport vehicles or fleets, even though the integration of these technical sciences offers improved safety and likely also cost efficiency. This historical fact needs to change.

2. **Culture of Change – Bridging Diverse Disciplines**

   There are two areas of focused culture change identified to enhance systems safety. One is the engineering and clinical interface described above. The other is the multi skilling versus siloed skills of the transport providers, as the number of providers has direct bearing on the selection and design of the vehicles. Even though there is a diversity of operational environments in neonatal transport -the practice of neonatal transport has inherently translated the stationary neonatal care environment, to a mobile setting. For the specialized neonatal vehicles, vehicle selection and the technical design of the environment has been fundamentally driven by health care providers, with limited and in many settings with no input from systems engineering, transport engineers, automotive safety engineers and transport human factors expertise. The result has been frequently costly and also hazardous environments that are often not consistent with current technical transportation safety science knowledge and practice. Furthermore, this transition from in-hospital to mobile environments has resulted in much higher ratios of providers to patients, and with limited clinical multi skilling of those providers in the USA compared to other nations. The high number of occupants, and the restricted focus in skill set of each of the occupants has also resulted in the USA in the use of very large heavy duty trucks – which in of themselves create a series of additional occupant safety and operational safety hazards in this setting. There is an important balance between the automotive safety aspects and the human factors and ergonomic issues. The number of occupants and their required operational tasks is fundamental to the design of the neonatal transport environment, as it is for the training of the providers in that setting and also the policies and procedures that govern the neonatal transport environment.

3. **Standards and Guidelines**

In contrast to common perception, there are very limited, if any protective standards or guidelines for the safe design and management of neonatal transport vehicles. Thus even more the imperative to access existing technical safety information that has had key involvement of automotive and human factors engineering expertise. Neonatal Transport vehicles are essentially exempt from much of the Federal Motor Vehicle Safety Standards (FMVSS) - http://www.nhtsa.gov/cars/rules/import/FMVSS/ - so it is important to appreciate that the usual bodies governing and overseeing safety of occupants in a vehicle, either passenger or commercial are not active in this arena. The Federal Motor Carrier Safety Administration (FMCSA) - http://www.fmcsa.dot.gov/, which oversees other commercial vehicles, also does NOT oversee the safety of neonatal transport vehicles. The FMCSA does have much valuable and useful information on its web site – including information on driver's hours of service and cell phone use. New automotive standards are now being developed by a number of organizations, some of which address safety of securing of equipment, and others are focused on other general aspects of ambulance vehicles. Standards and guidelines around vehicle selection, safe vehicle design, operation and management should be required for all neonatal transport programs.

4. **Fleet Management**

Medical dispatch is comprehensive in most neonatal transport settings. However, fleet management oversight and policies are also of fundamental importance. This is a field well established in the transportation industry, and industry standard practice for fleet safety is key. There are now a wide spectrum of available systems for monitoring of driver performance, that range from simple low cost mobile fleet management platforms on cell phones, to complex and more costly hardware systems for in-vehicle telematics. Regardless, it is paramount that a system be in place that provides both monitoring of the drivers performance and advanced warning of any hazardous practices and issues in real time. Fleet management guidelines exist from the American National Standards Institute - ANSI/ASSE Z15.1-2012 Safe Practices for Motor Vehicle Operations and should be followed by all transport services. That neonatal transport is exempt from FMCSA oversight, does not in any way mean there is any protection from the inherent risks of a transport vehicle or the laws of physics. See the 2013 National Academies Transportation Research Board overview of fleet management tools and medical transport (Youtube link to the TRB EMS Fleet Management simulcast and the handout).

5. **Innovative Vehicle Design**

Internationally neonatal transport vehicle choice has been focused on vehicle design safety and operational efficiency. The choice of the transport vehicle should include features such (a) Electronic Stability Control (ESC) to minimize loss of control of the vehicle and substantially prevent vehicle road departure, (b) Crashworthiness and occupant protection features of vehicle with occupant protection designed crumple zones to minimize harm to the occupants in the event of a crash and (c) high quality suspension to improve the ride for the occupants. These are standard features in many of the current fleets of vehicles used internationally and also available for use in the USA as neonatal transport vehicles. The interior should be designed

based on ergonomic and occupant protection principles such that it is possible for providers to perform essential clinical and other care whilst safely secured in the vehicle and without danger of serious injury. The neonatal transport incubator and equipment should also be secured similarly. In settings where the design is poor and there may be a head impact risk for providers, head protection such as a helmet should be considered, as for any environment where there is a risk of any occupational head injury. As recent events have demonstrated, simply purchasing the most expensive vehicle on the market does not in any way ensure that these safety aspects are being addressed. The layout of vehicle and seating position of occupants is key to optimizing the safety of the occupants. International examples of optimal layout, as modeled in the Innovation Design Module (INDEMO) Project by the EMS Safety Foundation http://www.INDEMO.info, make a strong effort to address these issues. Additionally, the more compact vehicles not only provide for a more safe occupant environment, and better reach to access equipment and perform clinical tasks, they are safer to handle on the road and also more efficient at controlling the vehicle interior ambient temperature and vibration.

6. **Neonatal Transport Incubator Systems and Design**

   The vast majority of presently used neonatal transport incubators are based on in-house box-like incubators with ancillary monitoring and therapeutic modules attached often in a crude manner to a "rig" or adult stretcher module. Additionally there are IV pumps and miscellaneous other medical equipment items. This combination of equipment is fundamentally not safe in a crash environment or even sudden deceleration. This approach, though viewed as "standard", does not take into account the key need for crash worthiness design focus. These hazards have been clearly demonstrated by researchers in the field. Whilst there exist some other approaches, the absence of meaningful safety testing and design standards in the USA leaves the safety performance of all these devices open to question. The need for a scientific basis for securement of the incubator, and as critically, safe securement of the infant in the incubator is fundamental. Further research, and a goal of this project, is essential to effectively addressing this important safety aspect.

   A new design for neonatal transport incubators is needed, one that meets the operational and system safety and occupant protection needs of these special groups of patients and providers. Improved design of the ambulance vehicle while essential, will not alone provide safety for the infant unless there are changes in design for the neonatal transport incubator. Also, in addition to the issues of crash worthiness and a safe biomechanical environment, maintaining the important needs for a neutral thermal environment and the abilities to provide intensive care and physiologic monitoring in transit must be addressed.

7. **New Systems Safety Technologies**

   There are new technologies that can directly impact and enhance the safety of neonatal transport. These include both technologies that make it safer to monitor patients, such technologies are developing rapidly in the current mHealth era, and also technologies that improve the safety of fleet operations (see item 4). Examples of these are more compact patient monitoring equipment, and wireless physiological sensors and transmission of patient

monitoring data aswell as automotive safe brackets for securing equipment and in-vehicle fleet safety monitoring tools, and alerts and alarms for seat belts when not properly secured.

8. **Risk Management**
Partnership with one's Risk Management experts is most helpful to ensuring the aforementioned safety concerns are understood and can be addressed. To optimize this conversation, seek out the existing material available in the public domain from independent organizations such as the fleet management guidelines from the American National Standards Institute - ANSI/ASSE Z15.1-2012 and the National Academies Transportation Research Board – for example the 2012 EMS Safety Systems, Strategies and Solutions Summit which address known hazards and potential causes of injury. There are a number of clear and basic hazards that are important to address in any vehicle. For example: prevent any unsecured equipment; avoid any unsecured occupants; position equipment so it is easily accessible; prevent predictable back injuries by storing any heavy items below waist height and consider head protection in vehicles where there is potential for head impact. When purchasing new vehicles, consider operational safety issues such as a vehicle that is crashworthy in its design, a vehicle that has ESC, a vehicle that has a loading height that will minimize back strain, and a vehicle that facilitates patient and equipment access and reach. Ensure that fleet management tools and policies reflect the optimal safety of the transport system.

In conclusion there is now much valuable and readily accessible information that fundamentally and conceptually addresses key elements that drive the safety of neonatal transport. An introduction to these key elements is covered briefly in this Preliminary White Paper which bridges a number of disciplines as we approach an understanding of exposure, culture of change, standards and guidelines, fleet management, innovative vehicle design, neonatal transport incubator systems and design, new systems safety technologies and risk management. The time has come to take a different and more comprehensive and interdisciplinary approach to augmenting the safety of neonatal transport.

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Scan this QR code with your smart phone or tablet or just go to this link

http://www.emssafetyfoundation.org/prelimSETONP.pdf

Resources and URL's

AAP Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients, 4th Edition, 2015
http://shop.aap.org/Guidelines-for-Air-and-Ground-Transport-of-Neonatal-and-Pediatric-Patients-4th-Edition-eBook

ANSI/ASSE Z15.1-2012 Safe Practices for Motor Vehicle Operations
http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI%2FASSE+Z15.1-2012&keyword=_inurl:webstore.ansi.org%23inurl:sku%3Dansi&source=google&adgroup=ANSI-Standards&gclid=CI6vpbm5t7sCFel9OgodkWUAqQ

EMS Safety Foundation Innovation Design Module, INDEMO Project - http://www.INDEMO.info

Federal Motor Carrier Safety Administration (FMCSA) – http://www.fmcsa.dot.gov/

Federal Motor Vehicle Safety Standards (FMVSS) -
http://www.nhtsa.gov/cars/rules/import/FMVSS/

National Academies for Science Medicine and Engineering, Transportation Research Board EMS Subcommittee ANB10(5) - 2012 EMS Safety Systems, Strategies and Solutions Summit
http://www.emssafetyfoundation.org/2012TRBSummitMultimediawithLinksBW.pdf

National Academies for Science Medicine and Engineering, Transportation Research Board EMS Subcommittee ANB10(5) Fleet Telematics Seminar, 2013 -
https://www.youtube.com/watch?v=cGjiRzGIMJs

Safety and Quality in Medical Transport Systems – CAMTS, John Overton & Eileen Frazer, 2012
http://store-t1h3x1c.mybigcommerce.com/safety-and-quality-in-medical-transport-systems/

** We want your feedback! **

Public Comment is open until July 30th 2016 –
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www.EMSSafetyFoundation.org/SETONP-PublicCommentForm.htm