



STATE OF MAINE
 DEPARTMENT OF PUBLIC SAFETY
 MAINE EMERGENCY MEDICAL SERVICES
 152 STATE HOUSE STATION
 AUGUSTA, MAINE
 04333



JOHN ELIAS BALDACCI
 GOVERNOR

ANNE H. JORDAN
 COMMISSIONER

JAY BRADSHAW
 DIRECTOR

Maine EMS
 May 19, 2010
 Minutes

<p><u>Medical Directors Present</u> – Diaz, Sholl, Cormier, Goth, Coor, Busko, Kendall, Pieh</p> <p><u>Medical Directors Absent</u> –</p> <p><u>Staff Present</u> – Jay Bradshaw, Kerry Pomelow</p> <p><u>Guests</u> – Scott Cook, Shawn Evans, Ginny Brockway, Rick Petrie, Dan Batsie, Eric Michaud, Brian Chamberlain, Chandler Corriveau, Stanley Grass, Ben Morey, Josh Stewart, Chris Baker, Vivien Silva, Casey Bearor, Mike Senecol, Micheal Schmitz, Chris Pare</p>		
March 2010 Minutes	Reviewed -	<p>Motion to Accept – Kendall</p> <p>Seconded – Cormier</p> <p>Approved – All</p>
ME EMS Update	Diaz – Hall of Flags ceremony tomorrow	
IRB Session Review	<p>Dr Irwin Brodsky – Endocrinologist at MMC – ME Center for Endocrine and Diabetes – Career in DM – prior at U of Illinois. Project came from a patient with prolonged cognitive dysfunction after hypoglycemia – Diabetes Control and Complications Study – says that there are no prolonged cognitive deficit. This patient encounter generated questions about the brain sequela from hypoglycemia and the potential for <i>intermediate</i> brain sequela. Do pts with hypoglycemia, LOC +/- Sz have brain sequela in the intermediate phases after the event. He has submitted a grant to the NIH proposing to study patients in the weeks after the event – in collaboration with the neurologists that published the DM Control and Complications study (who noted that the patients studied in his project were studied after 2 years AND they were looking for major neurologic outcomes). Proposed: use a computerized cognitive testing tool called IMPACT</p>	<p>Motion to accept – Sholl</p> <p>Seconded – Kendall</p> <p>Agreed – Pieh, Goth, Busko, Coor</p> <p>Abstained – Cormier</p> <p style="text-align: center;">Approved</p>

(used to measure neurologic dysfunction after concussion). Initial proposal was to test IMPACT in the population and gather preliminary data on these patients. NIH got back and wanted to begin looking directly at the patient outcome. Looking to enroll 10 patients with severe low blood sugar and resuscitated with dextrose or glucagon. Contact these patients after the event and use the IMPACT tool within 24-36 hours then test 1,2 and 4 weeks later, after the event. Asking for a waiver of initial written consent in order to contact a subject asking for interest and if interested, going through a formal consent process. ME EMS data will be seen by the investigators only and de-identified data for the project will be used. Possible that summary data would be published depending on results.

Pieh – Are we asking for a waiver only in the identification phases BUT a consent (and assent) to be done at a later point? YES

Bradshaw – Discusses the legal issues in statute for accessing the ME EMS Data. We are prohibited to release data that would allow identification of patients. A solution would be to identify the patients ourselves and make first contact then pass the willing patients along to the research group.

For the MDPB members – Informed consent provides that a potential human subject, to the extent capable, be given the opportunity to choose what shall and shall not happen to his or her body or information. Consent is “informed” when a research investigator has provided a prospective subject or his/her authorized representative the information, in language understandable to him/her and under circumstances that provide sufficient opportunity to consider whether or not to participate in the research and that minimize the possibility of coercion or undue influence. Information shall include the risks, benefits and alternatives of participation, an opportunity to ask questions and have such questions answered in full, and ensuring that the potential subject understand that participation is entirely voluntary.

The MMC IRB has vetted this Informed Consent. This consent has all the elements for patient protection.

Questions surround informed consent:
Can not ask a patient recently resuscitated from a

	<p>hypoglycemic sz of unresponsive episode for consent.</p> <p>Only invasive procedure is a FSBG at the time of cognitive testing to assure the test is valid. Also a vibratory test as (in children) to identify neuropathy. These done AFTER consent.</p> <p>Do we support his through an IRB function (there are some operational issues including accessing the data base ALSO do not have a way to “scrub” our data – once we send information, the receiver can see everything).</p>	
<p>New Devices</p>	<p>Petrie – Eject System – request to review a new device. Effects standby coverage of race and motor tracts. NASCAR has approved the EJECT system for head protection. Services that provide standby coverage for these events will have to use these AND these devices may become more widespread in use. Device is a “balloon” with a pigtail that exists the helmet. Once placed, two ways to remove the helmet – a hand pump or a CO₂ cartridge. Can be mounted in the helmet prophylactically or can be placed after an accident.</p> <p>Petrie demonstrates the device both with Hand Pump and with CO₂ cartridge.</p> <p>Diaz - Kit costs \$300 and there is an online certification process. Along with the value – what is the educational effort behind this? Website is (www.shockdoctor.com) and www.ejectsafety.com. Will work on any full-faced helmet. Rick reports that MA has begun discussions of placing these in school age children football helmets.</p> <p>Diaz – does this really make removal easier? Petrie – mentions probably not BUT our crews will run into these as they are gaining acceptance.</p> <p>Coor – if we use the device, is there any data on the safety? Are these safe to use? Petrie – NASCAR has deemed so... If you suspected a head injury or if the helmet is damaged, suggests we do not use the device.</p> <p>Busko – perhaps there are 2 populations. Those who preinstall these and those in which EMS crews carry and use them. Perhaps in the first group, this makes sense. The devices are installed and there should be</p>	<p>Motion to Table until see safety data – Goth</p> <p>Seconded – Pieh</p> <p>Approved – All</p>

	<p>on the job training.</p> <p>Diaz - Three groups – 1) preinstalled, 2) installed after the accident, 3) damage to the helmet (including penetrating injury). This was brought forward for the group in first category. Is the request for that group only OR for general use.</p> <p>Diaz – How do we ensure education for the use of the device? Do we rely on the job training or do we create a module for the use of these devices? Batsie – like any other device, the impetus would be on the group using them. BUT if we endorse these for general use, we would have to make an awareness statement for the entirety.</p> <p>On the website – there is no suggestion of data backing the device up.</p> <p>Motion to table - Accepted</p>	
Neonatal Transport	<p>Diaz – Question came to us about requirements for Neonatal transport. Do we have criteria on how a neonate is strapped down? The MDPB does not typically discuss the mechanism of anchoring patients. Question is “requirements for the anchoring of neonatal incubators? Are there state requirements?”</p> <p>Petrie - In LifeFlight’s case they have to be approved by FAA. Maine does not follow Triple K specs. Rules speak about ambulances and heights.</p> <p>Brian – NHTSA – looking at a better mechanism for securing litters.</p> <p>Diaz – this is probably NOT an MDPB issue and probably lives in rules and regulations. Could contact NHTSA (Drew Dawson) and inquire at that level.</p>	Steve and Jay to contact NHTSA for more details.
Protocol Review	<p>1) Gold</p> <p>2) Pink</p> <p>See Separate Notes</p>	
IRB Process and Training – Reminder	<p>Will receive a certificate that should be sent to Steve. Here is the website: http://phrp.nihtraining.com</p>	
Protocol Review Process	<p>Following Sections –</p> <p>Blue - Tim June</p> <p>Red – Marlene July</p>	

	<p>Gold – Jonnathan May Green – Peter July Yellow - Kevin June Pink – Colin May (Colin to tee up his discussion at the retreat and we will bring this to the group in May)</p> <p>Proposal from last meeting – to extend the time of the MDPB and to do two sections per month. (MDPB 9:30 – 13:30 starting in May)</p> <p>New Proposal – once this process finished, Matt/Jay/Steve will compile changes fro internal and external review over August. The MDPB will take August off – then reconvene in Sept with a goal of fine tuning one section each month with internal and external comments.</p>	
Hand Off forms	<p>Goth - Reviewed discussion from last month. Proposes a form using the SOAP format. Sholl – we discussed last month creating a list of necessary information and that multiple forms couth then be used locally as long as the form carried those elements.</p> <p>Goth – this is more of a concept.</p> <p>Busko – “This form is for informational purposes only. It is not to be included in the medical records.”</p> <p>Diaz – Peter – send this out and the group will review.</p> <p>Petrie – there are other forms out there – these other forms list required information.</p> <p>Decision to NOT endorse specific requirements at the state level BUT to allow for specific hospitals to request information in the hand off process through these forms. Allow regional medical directors to act as mediators.</p> <p>Petrie – the position that we do need to take –</p> <p>Motion - Services need to incorporate written communications at the time of patient hand off. If this communication is not in the form of a completed run report, then hospitals can determine the information they require. These hand off forms are not a substitute for a completed medical record. These forms are also</p>	<p>Motion – Sholl</p> <p>Second – Kendal</p> <p>Approved – unanimous</p>

	<p>not mandated as patient medical records unless the hospital deems so.</p> <p>Motion Accepted</p> <p>Trying to develop an intent of transparent and clear information</p>	
Old Business		
Airway Subcommittee		
HART Update		
MEMS Education		
MEMS Operations		
PIFT Teaching to Hospitals		
MEMS QI		

Next Meetings – June 16, 2010 – 9:30 – 2:00

Maine EMS QI –

HART Committee – 3pm – 5pm