

Interim EMS Clinical Practice Workgroup
Meeting Notes
October 19, 2011

Attendees

Keith Hermiz, Andrea Ochs, Matt Vinci, Dan Wolfson MD, Mark Podgwaite, Kate Soons, Bill Edson, Bernie Tolmie, Mark Considine, Ed Sullivan, Michael Wright, Steve Salengo, Chris McCarthy, Troy Madigan, Jim Finger, Keith Baker, Bill Hathaway, Scott Brinkman, Adam Heuslein, Ray Walker, Chris Bell

Introduction

This work group will hold a series of meetings – there is a lot of work to do:

- Agree on principles to guide the waiver process
- Develop a framework for reviewing waiver applications
- Review new waiver requests
- Review waivers that are currently in effect and provide follow-up as needed

The EMS office has two goals: protecting the public and serving the EMS community. These principles need to be balanced in judging the worthiness of waiver requests.

Based on waiver requests already received by the EMS office, Chris expects 6-12 new requests a year.

Adopting the new scope of practice model

What new skills will be allowed and what training will be provided?

The interim transition education work group will determine what the transition program will look like and roll it out quickly. Waivers will be considered in the context of those programs.

Waiver review process

- We will develop a new process from the ground up
- Waivers will be evaluated by the clinical practice work group which will make a recommendation to the Health Department to approve, deny or approve with conditions. The group will need representation from all interested parties to reach good decisions.

Things to consider in reviewing waiver requests

- What is the need for the waiver?
 - o How frequently would it be employed, and is it often enough to ensure quality?
 - o What is the transport distance?
 - o What is the time and criticality factor?
 - How high is the risk of harm compared to the benefit?
 - Are the right controls in place?
- What training will be required?

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- Can we use existing training at a higher certification level to determine the standard?
- What is the plan for refresher training?
- What is the level of involvement of medical direction?
 - What QA/QI will be employed?
 - How will data be collected and evaluated?
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- What research exists to support the waiver request?
 - What evidence is there about the risk of harm?
 - Where and how has the proposed procedure/medication been implemented?
 - What evidence of statistical and clinical significance is there?

Research

- The group recognized that obtaining adequate evidence will be a challenge. Applicants will need to do their best using existing research
- Data from ED electronic records is probably not accessible – each hospital has its own system; there is not a central statewide database, but SIREN is coming
- About 20% of VT ambulance services are using SIREN now; due to the size of the agencies now reporting, more than 20% of the EMS runs are going into SIREN.
- We will need to use NEMESIS (national EMS) data because the VT data set is probably going to be too small
- Patient consent can be a challenge. Chris described “community consent” where the public is informed through public meetings and notices; people can then exclude themselves. An Institutional Review Board (IRB) is probably required, but it’s not easy or inexpensive
- District 3 (Fletcher Allen Health Care) has had several trials denied by the IRB (example: ET vs. King Airway trial was denied because the unconscious patient could not provide consent); they could only use community consent.
- IRB cannot provide the answers; legislative fix is needed, perhaps at the federal level
- Using existing studies can be a problem if they don’t adequately reflect Vermont. For example, using data from an urban study might not be relevant to rural areas.
- UVM has an EMS Research program that could be a resource. Dr. Wolfson reported that it is a great program currently engaged in 30 projects. Students of the research course staff the ED to collect data.

Waiver requests already in the pipeline

- All waivers currently under consideration are on hold until this work group has established a framework for reviewing them. Some requests may need to be resubmitted using the new format – a determination will be made case-by-case.
- EMS staff will conduct an interim review to determine if the requests already are covered by current protocols

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- All waivers needing review will come to this work group to make recommendations

Goals

- Develop standard paperwork and a consistent review process
- Keep the process open and transparent; no backroom secrecy
- Establish clear guidance for necessity of a waiver:
 - o Anything that exceeds the scope of practice as defined in rules or protocols (or in the new standards) will need a waiver
 - o New product designs that improve an in-scope intervention probably will not need a waiver
 - Protocols and rules are written to be intentionally generic to accommodate several brands and models

How the group will function

- The composition of the Clinical Practice work group is not set in stone. It may have a different set of participants at every meeting. After the Act 142 committee has made its recommendations and a decision is made about instituting other EMS advisory committees, more consideration will be given to the make-up of this group. District medical advisors and ED directors have been invited to participate and will be asked again.
- Applicants will be invited to attend meetings where their requests are reviewed
- The state medical director will attend these meetings and be part of the EMS office review
- Copies of applications will be provided in advance on the website
- Commissioner Chen will be involved; presently, Chris is the commissioner's designee

The role of the district

- Who will be required to sign waiver requests: District medical advisor? District board chair? Squad medical advisor?
- Some in the group indicated that the district board is an unnecessary level of review that will slow the process down; the district medical advisor's approval should be sufficient. Chris allowed that it didn't have to be either/or. Perhaps the request wouldn't need sign-off from the district board, but the requesting agency should at least present the request to the board.

What information should the applicant provide?

Descriptions of:

- the intervention and why it is needed
- research that supports granting the waiver
- training required
- medical direction that will be provided
- cost and time implications for equipment, supplies and training (particularly if it's a district or state-wide waiver that affects several agencies)

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General questions

In cases where medications are restricted by rule or protocols, will this group be able to propose rule and protocol changes?

Will the waiver review process consider how to protect proprietary or trade secrets? The waiver process is probably subject to open records laws, but there might be provisions for exceptions. Perhaps we should see how IRBs handle these sorts of requests.

What about complicated requests that might require ethics review? Perhaps the service can work with their hospital's IRB as a resource.

Next steps

EMS staff will:

- draft guidelines for determining when a waiver is necessary
- draft an application form
- instructions for applying for a waiver
- set a date for the next meeting – in about 4 weeks.

Feel free to contact Chris Bell with questions and comments.