

Monterey County EMS System Policy



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PILOT PROGRAMS – OPERATIONAL, CLINICAL, EQUIPMENT

I. PURPOSE

- A. To define the process by which the Monterey County EMS Agency plans, develops, implements, and monitors Pilot Programs.
- B. Pilot Program studies are typically small scale and short term for the purpose of evaluating quality indicators and/or operational improvements for local EMS policies and/or protocols.

II. POLICY

- A. The EMS Agency Medical Director and EMS Director must review and approve of all Pilot Programs prior to implementation.
- B. Projects involving any of the following will be considered as research and require approval according to the Monterey County EMS Agency's Research Policy:
 - 1. Changes in the State EMS Authority EMT-P Scope of Practice or untested intervention.
 - 2. The goal of the project is to test a hypothesis.
 - 3. The investigators intend to submit the results for publication in a professional journal.
 - 4. When questions arise as whether a project is quality improvement versus research, the investigator will consult with the Institutional Review Board.
 - 5. When a new piece of equipment, not previously used in the county, is being evaluated.
- C. The Pilot Program Investigator(s) shall submit a Pilot Program Proposal to the EMS Agency at least three months prior to the planned implementation date in order to allow time for Medical Advisory Committee review.
 - 1. The EMS Agency shall review the Pilot Program Protocol and solicit EMS Stakeholder input through the EMS Agency's Policy Development Review Process.
 - 2. Investigator(s) must submit the Pilot Program Proposal according to the following format:

- a) Background/Significance: Describe the rationale for the Pilot Program, citing relevant research. Identify what questions remain and how the proposed Pilot Program will address these questions. Specify how the Pilot Program may improve the quality of care in the EMS System.
- b) Objectives: List the objectives upon which the outcome of the Pilot Program will be based. Identify the predictor and outcome variables and the expected outcome of the Pilot Program.
- c) Design/Methods: Identify the type of study, the outcome variables to be measured and how each is an indicator of quality of care. Describe the methods used to collect the data and avoid bias.
- d) Evaluation: Describe the data management and statistical methods that will be used to evaluate the data. Include methods used to minimize bias and standards or benchmarks proposed to accept the conclusions.
- e) Conflicts of Interest: Identify and describe any proprietary, or financial, (including salary, consultant payments, honoraria, royalty payments, dividends, loans, or any other payments or consideration with value) conflict of interest.
- f) References: Attach copies of references cited in the protocol.

III. PILOT PROGRAM REVIEW PROCESS

- A. The EMS Agency Director and Medical Director shall review the Pilot Program Protocol and will either forward the protocol to the Medical Advisory Committee for review or return to the Investigator for modifications.
- B. The Medical Advisory Committee will review the protocol, provide feedback and vote to recommend approval, modifications or disapproval of the proposed Pilot Program.
- C. The EMS Agency Medical Director will approve or deny the implementation of the Pilot Program. If approved, the data collection period is one year.


IV. REPORTING PROCESS

- A. Monthly Reports: The Pilot Program Investigator shall submit monthly reports to the EMS Agency on the 15th day of each month. These reports must summarize the progress of the program and evaluate available outcome data from the previous month. The need for quarterly reports in addition to or instead of monthly reports will be determined by the EMS Agency Medical Director.
- B. Final Report: At the end of the one year data collection period, the Investigator must submit a final report to the EMS Agency Medical Director. The final report must include a summary of the Pilot Program including the objectives, methods, data analysis of the outcome variables, the limitations of the study and the conclusions. The final report is due no later than the 15th day of the 3rd month following program completion.

V. COMPLETION OF PILOT PROGRAM

- A. At the completion of the Pilot Program, the EMS Medical Director will assign one of the following designations:
1. Approved
 2. The Pilot Program demonstrates improved quality of care. EMS policies and/or treatment protocols may be revised pursuant to EMS Agency Policy.
 3. Extended (up to one year)
 4. There is insufficient data to evaluate the impact of the Pilot Program on quality of care and the data collection period must be extended.
 5. Closed
 6. The Pilot Program does not demonstrate an improvement in quality of care.
- B. The EMS Agency will present the results of the Pilot Program and the recommendations of the EMS Medical Director to the Medical Advisory Committee.

END OF POLICY


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