The National EMS Advisory Council

Submitted on March 29, 2012

Committee: Systems

Title: Evidence Basis for EMS Systems Design

Issue Synopsis

A: Problem Statement

Emergency medical services (EMS) systems in the United States are local by nature. EMS is delivered (and often delivered differently) in virtually every city, community, county, tribal land, and parish in the United States. Many of these systems are comprised of multiple, autonomous providers, each with goals and strategies that, while appropriate for that provider, may be inconsistent with the overall goals of both the local EMS system and the healthcare infrastructure. Conversely, other communities deliver a highly integrated level of EMS with most or all agencies guided by a universal set of system goals and guiding principles. Because EMS systems are inherently local, the structure, function, and level of integration with other EMS and health care providers can vary greatly.

The heterogeneity of EMS systems intuitively leads to a high variability of both care and costs throughout the country. At least a part of the variability is the result of the structure of EMS systems, and part is related to the paucity of evidence-based outcome research. Further, pursuing the medical evidence for different approaches to prehospital care is often done without in-depth economic analysis. That is why researchers, medical providers, system administrators and others are increasingly focused on evidence-based guidelines for EMS system design—in the context of both medical and economic outcomes.

The National EMS Advisory Council adopted the EMS Systems Committee report¹ in September 2009 that contained a number of recommendations, including

- 1. Support a federal effort to expand, enhance, and fund EMS research based on operational, financial, and medical outcomes criteria.
- 2. Develop and publish key performance indicators (KPIs) for EMS systems to measure and monitor performance. Use NASEMSO Performance Measures document as basis for performance standards.
- 3. Share committee recommendations with Council on Emergency Medical Care (CEMC), Emergency Care Coordinating Committee (ECCC), Federal Emergency Management Agency (FEMA), and Federal Interagency Council on EMS (FICEMS) so that EMS is not left out of the discussion on health care reform.

Following that recommendation the EMS Committee was charged in identifying evidence-based

guidelines for emergency medical services. The committee work following that discussion considered two major components related to the nature of EMS evidence—the evidence supporting medical outcomes based on interventions delivered by prehospital providers, and the evidence related to costs in the EMS system that support those activities. Medical evidence and costing analysis allows EMS administrators and others to prioritize the activities within their EMS systems to deliver the best possible outcomes at the most reasonable or perhaps the lowest cost.

EMS System Definition. An EMS system has many definitions. In the medical community, a system of care is a comprehensive integrated framework of providers that are collectively aligned to provide the highest likelihood of positive outcomes for patients. Notable systems of care exist in the mental health and pediatric communities. In EMS, stakeholders have witnessed systems of care begin to emerge in ST elevation myocardial infarction (STEMI) care², trauma, and stroke care³, but EMS has not always been designed with "system based" structure. Questions are beginning to emerge about whether some of the structures that currently exist may not be effective in improving patient outcomes. According to the Institute of Medicine Report, EMS at the Crossroads⁴, "While there is little evidence to guide localities in designing their EMS systems, there is even less information on how well any system performs and how to measure that performance." Because integrated systems of care can improve outcomes, NEMSAC has determined that evaluating EMS system design (or maybe more appropriately "EMS systems of care") and its impact on patient and economic outcomes, is an important issue for emergency medical care in the United States.

EMS systems, perhaps because of their functional heterogeneity, are poorly defined. In its 2009 EMS Systems Committee Report, NEMSAC's System's Committee adopted the NFPA 450⁵ definition of an EMS System. According to the NFPA, an EMS system is,

"A comprehensive, coordinated arrangement of resources and functions which are organized to respond in a timely, staged manner to medical emergencies regardless of their cause."

Yet in the research, other definitions of EMS system have also emerged. For example, in his EMS costing analysis, Lerner⁶ identified an EMS system as the,

"EMS system as it responds to acute, unscheduled health care delivered outside the hospital within the setting of a system that deploys health resources in response to a request for emergency medical care, which includes lay responders, public safety, and EMS providers who participate in this response and the system within which they respond."

The National Association of State EMS Directors (now called the National Association of State EMS Officials—NASEMSO) and the National Association of EMS Physicians (NAEMSP) created a joint position statement on EMS⁷, including a definition for EMS Systems:

"An emergency medical services system is a comprehensive, coordinated arrangement of resources and functions which are organized to respond in a timely, staged manner to targeted medical emergencies, regardless of their cause

or the patient's ability to pay, and to minimize their physical and emotional impact."

The similarity between the NASEMSO/NAEMSP document and the NFPA document is no coincidence. The NFPA adopted the major components of the NASEMSO/NAEMSP as part of its consensus-based document development.

One category of the existing research focuses on specific components of EMS systems such as response time; integration of various treatment methods; the effect of intubation, and the implementation of various pharmaceuticals and other interventions. In addition, episodic-based research examines treatment of specific episodes of patient diagnoses, such as ST-elevation myocardial infarction, stroke, and trauma. What the studies, by and large, have not described is how *integrated EMS systems of care* (or more simply "EMS Systems") can improve medical outcomes or create economically sustainable emergency systems of care.

That is why the National EMS Advisory Council has identified a need to determine whether the design of an EMS system has evidence to support the design of the system. The Systems committee has identified two primary components for which there are opportunities to develop EMS system with the opportunity to make improvements in EMS system design: medical evidence related to patient outcomes, and economic evidence that supports prioritization of potential design components.

B: References

EMS prehospital research related to EMS system design.

Prehospital emergency medical systems design takes several forms. First, the medicine provided by field providers must be integrated with emergency room care (or more accurately hospital care), to track medical benefits related to patient outcome and survival. Second, the medicine provided by various field providers must be considered in the context of economics to allow communities to prioritize specific EMS efforts over others. Importantly, these issues are related. If an intervention is shown to provide superior medical performance, it is rarely useful if it is too expensive to implement. An anesthesiologist on an ambulance may be able to demonstrate superior airway care for example, but deploying that resource is hardly feasible in modern EMS systems.

However, if an agency is focused on how integration and evaluation of field operations can improve patient and economic outcomes, one must look at operational questions such as how to deploy and organize resources to achieve the best possible results, how to staff fire and ambulance apparatus, (i.e. one paramedic or two an on ambulance; three, four or five personnel on a piece of fire equipment, etc) early arrival time of first responders or ambulance providers, integrated quality assurance, integrated medical protocols, first responder integration of what is traditionally ambulance operations (such as 12-lead ECGs), citizen intervention with CPR and AED use, and so on. These questions are critical as local system administrators and managers engage in efforts to align personnel and deployment to the best possible outcome for patients.

Selected Medical Outcomes Research

NEMSAC adopted the white paper, *EMS Makes a Difference*⁸, in December 2009. That document describes the medical outcome and downstream economic benefits provided by emergency medical care. Specifically, the report focuses on medical research throughout the nation and the world related to field provision of emergency medical services. The research described in this and other documents has focused on specific components of EMS systems—such as response time; integration of various treatment methods; the effect of intubation, pharmaceuticals, and other interventions; and trauma care. What the studies, by and large, have not described is how *integrated EMS systems* can improve outcomes, enhance provider safety, or create economic sustainability in emergency systems of care.

In January 2012, the National Quality Forum (NQF) produced the Regionalized Emergency Medical Framework⁹ that considered systems of care as method to improve medical outcomes across geographic areas, much like trauma, neonatal care and poison control have done in the last two decades. The consensus-based report argues for an "episode of care" (EOC) model as method to measure performance across service units and over time. Importantly, it focused on the contact points between providers and recognizes that care transitions may impact outcomes as a patient moves through the healthcare delivery systems. Using a modified EOC method, systems can make comparisons across institutions and then make improvements to improve services.

The NQF document supports six significant domains of performance measurement: 1) capability, capacity, and access; 2) recognition and diagnosis; 3) resource matching and use; 4) medical care; 5) coordination of care; and 6) outcomes. To assist in the implementation of the performance domains, the document establishes guiding principles that are transferable across EMS systems. The document calls for additional research to identify new performance measures, and seeks to identify specific performance measures for the transitions between healthcare providers. The document does not consider economic or financial outcomes as a means to measure provider performance in healthcare systems.

Between 2002 and 2006 the National Association of State EMS Officials (NASEMSO) and the National Association of EMS Physicians (NAEMSP) collaborated on a consensus-based project to enhance the depth of performance measures available in the EMS community. This project—The EMS Performance Measures Project: Recommended Attributes and Indicators for System/Service Performance ¹⁰—first determined the need for additional EMS performance measures and then identified 35 consensus-based measures. Importantly, the EMS Performance Measures Project aligned the measurement methods with those same methods typically used in other areas of the healthcare system, such as the Joint Commission on the Accreditation of Healthcare Organizations. Those measures also delineate the formulae and data elements necessary to calculate the performance and also to ensure that the data elements can be applied in multiple systems and agencies.

The EMS Performance Measures Project contains 18 clusters and 35 performance indicators. Many of the indicators are related to time performance (i.e. response time, time to defibrillation, time to first EKG, transport time, etc.) and some of the indicators are related to safety, and customer surveys, and transport. The report does establish one financial criterion—Per Capita

Agency Operating Expense—however the committee did not proceed with the performance indicator because of the measurement complexity. This document later became the EMS Performance Measures document published by NHTSA in 2009¹¹.

The Institute of Medicine published a landmark document in 2006 entitled Emergency Medical Services at the Crossroads⁴. The IOM report on regionalization of emergency care noted that "[b]ecause not all hospitals within a community will have the personnel and resources to support the delivery of high-level emergency care, critically ill and injured patients should be delivered specifically to facilities that have such capabilities."

"The committee's vision expands the concept of an inclusive trauma system to include all illnesses and injuries, as well as the entire continuum of emergency care—including 9-1-1 dispatch, prehospital EMS, and clinics and urgent care providers that may play a role in emergency care."

The IOM report made a number of observations related to EMS in the United States. First, the Institute noted that throughout the country, EMS systems have insufficient coordination. Systems are highly fragmented, with multiple agencies serving single population centers without acting cohesively. Transport coordination within regions is limited making the management of patient flow difficult or even impossible. Handoffs between providers is ineffective and important patient information is either ineffective or missed.

The IOM also concluded that the response time of ambulances is highly disparate in the country with differences related to demographics, terrain, traffic, management expertise, and other factors. Importantly, the difficulties with communications, coordination and organization of EMS systems make response time standardization difficult at best.

There is very little known about the quality of care in the United States according to the Institute of Medicine. Because there are no nationally agreed upon measures of quality and virtually no accountability for performance of EMS systems. The IOM states that, "While most Americans assume that their communities are served by competent EMS systems, the public has no idea whether this is true and has no way to know."

According to the IOM report, "the evidence base for many practices routinely used in EMS is limited. Strategies for EMS have often been adapted from settings that differ substantially from the prehospital environment; consequently, their value in the field is questionable, and some may even be harmful. For example, field intubation of children, still widely practiced, has been found to do more harm than good in many situations. While some recent research has added to the EMS evidence base, a host of critical clinical questions remain unanswered because of limited federal research support, as well as inherent difficulties associated with prehospital research..." In addition to other recommendations, the Institute of Medicine recommended that NHTSA should "convene a panel of individuals with multidisciplinary expertise to develop evidence-based model prehospital care protocols for the treatment, triage, and transport of patients."

Two international organizations, the International Association of Firefighters, and the International Association of Fire Chiefs (IAFC) have developed a consensus document that

describe the agencies' recommended indicators for the measurement of EMS systems ¹². These 15 quality measures are designed with specific definitions and performance descriptions and provide users with methods to measure that performance. Yet these measures are limited by their ability to measure performance in the system, rather, they measure specific agencies' performance. As such, in systems with multiple providers the method may not adequately capture other autonomous organizations—i.e. they measure agencies rather than systems.

The instrument articulates 15 quality indicators, describes the background necessary to evaluate quality, and explains existing standards. The indicators include: call processing time, turnout time, defibrillation time to first shock, employee turnover, patient outcome, protocol compliance, deployment of mobile resources, staffing and employee illness and injury. The measurement instrument will provide system leaders an improved way to collect relevant data and to report on that data in the future.

Some researchers have identified the importance of the systems approach to improving episodic care. David Cone discusses the outcomes of the 2010 Academic Emergency Medicine consensus conference at which a breakout group focused on prehospital issues related to integrated networks of emergency care¹³. At the session, the participants describe the success of specific types of integrated EMS system networks, such as treatment for burns, stroke, ST-segment elevation myocardial infarction and post cardiac arrest resuscitation.

Yet the authors recognize that improving EMS systems infrastructure and integration is critical to improving outcomes, "...this development cannot proceed optimally without considering how regionalization affects EMS and the prehospital infrastructure that must be in place for regionalization to move forward. The science evaluating and guiding the development of such systems is variable—fairly advanced in some areas, barely nascent in others." The infrastructure to be developed includes a systems-based approach that focuses on 1) which patients, 2) which receiving facilities, 3) maintenance of the system, 4) bypassing non-specialty centers, and 5) methods of transport.

Of particular interest to the authors, was that there are no existing categorization or typology for EMS. Typically EMS providers are licensed by level, and vehicles are licensed by type, yet there is not a categorization of EMS systems. The authors opine, "Additional research is needed to create an evidence-based, comprehensive and more uniform set of guidelines to govern the delivery and practice of prehospital emergency care."

In 2005, Dr. Ian Stiell published cardiac arrest and other research from the Ontario Prehospital Advanced Life Support (OPALS) study ¹⁴. The OPALS study represented one of the largest cardiac arrest research analyses of its time and identified both outcome and cost information. Dr. Steill reported that, for cardiac arrest, initial CPR and rapid defibrillation were more highly correlated to survival of cardiac arrest than advanced life support arriving within 8 minutes. Further, advanced life support systems are expensive and their benefit has never been established for out-of-hospital cardiac arrest. Essentially, the first three links of the American Heart Association's Chain of Survival are supported in the OPALS study while the fourth—ALS intervention—is not. The methods of calculating costs are not well described and the study focuses only on the most critical component of prehospital medical care—cardiac arrest.

During early 2007, NHTSA conducted a national telephone survey to "obtain data on attitudes, knowledge, and self-reported behavior." Though one part of the survey seeks responses related to motor vehicle occupant safety, the 2007 survey also included community attitudes related to EMS and 9-1-1 system access. The surveys provide information about the importance of EMS to the community (compared to police and fire services) and the demographics of people who are willing to pay more for EMS or 9-1-1 services. According to the report, "the majority of the public believes that EMS is at least as important as police and fire services." In addition, 63 percent of survey respondents are willing to pay more for EMS services to improve EMS equipment and training.

In 2011, Daniel Beskind and other researchers evaluated the trauma research literature and made recommendations about risk adjustment and outcome measures for research. The published their findings in an article entitled, Risk Adjustment Measures and Outcome Measures for Prehospital Trauma Research: Recommendations from the Emergency Medical Services Outcomes Project, in Academic Emergency Medicine¹⁶. The literature review consisted of nearly 5,000 articles and nearly 100 risk adjustment or outcome measures. They determined that despite the number of articles, only one measure met the standards for a Level 1 (strong) quality of evidence status and 12 measures met the standard for Level 2 (promising). The authors concluded that the lack of reliable measures available for outcomes research would require additional effort to establish better evidence of the Level 2 measures and develop new evidence.

The U.S. Department of Health and Human Services (HHS) has considered the historical development of trauma systems throughout the United States and the approach to trauma systems that make trauma more survivable today that ever before. Beginning with The Highway Safety Act of 1966¹⁷, followed by the Emergency Medical Services Systems Act of 1973, the federal government has been engaged in systematic attempts to make improvements to specific patient care episodes related to trauma. Later, in 1992, the agency emphasized the need for a fully inclusive trauma care system in its Model Trauma Care System Plan (MTCSC)¹⁸. This plan emphasized the need for fully inclusive systems of care; although those care systems were related solely to injured patients. Importantly, the trauma system planning and evaluation process considered both the quality and evaluation process as well as the system finance issues related to that evaluation. Yet while the HHS document seeks to include all levels of providers (including first responders, transport services and even law enforcement) in the evaluation of systems, the evaluation is limited to how trauma care is delivered and leaves out the issues of both medical and other events.

EMS Research Related to the Cost and Efficiency of Interventions.

Some EMS research has focused on the patient-centered outcome of medical interventions, while other research has focused on the financial or efficiency. Importantly, EMS and other medical data must be evaluated on both. Typically, patient outcomes are measured followed by determinations of efficiency (inputs divided by outputs). Research related to outcome feasibility is identified in several EMS efficiency studies.

The Agency for Healthcare Research and Quality (AHRQ), contracted for a research study to evaluate the relationship between quality and efficiency in medical care systems¹⁹. Results of AHRQ's findings include the nature of the relationships between quality measures and efficiency

measures. Importantly, the research found that a number of measures of quality in EMS systems do not consider efficiency and cost effectiveness; similarly, virtually none of the standardized measures of efficiency include the dimension of quality. This presents a particular challenge for EMS agencies as they attempt to determine the evidence basis for specific interventions while not knowing the cost effectiveness of those interventions. As systems of care with multiple autonomous providers, the nature of findings for both evidence and quality must be carefully explored.

In 2006, Brooke Lerner evaluated the literature related to the economic value of out-of-hospital care ²⁰. In its research, the group concluded that there was "a paucity of out-of-hospital literature that addresses cost and economic value." The authors described that the process of evaluating efficacy and effectiveness of competing treatment regimens in EMS should conclude with an economic evaluation. Unfortunately, few existing studies did so; therefore the objective of the study was a systematically review published economic evaluations of out-of-hospital care to assess its economic value.

Lerner articulated, "economic evaluations are most useful when there is evidence that an intervention is effective." Unfortunately, because so few effectiveness studies exist, communities are unable to prioritize the use of limited EMS resources. According to the literature reported in the study, four economic factors—quality adjusted life year (QALY), cost per life saved, incremental cost, and cost per year of life saved. A weakness of the analysis was the age of the documentation of EMS costs—no study reviewed was more recent than 2002.

In 2007, Lerner and others published a consensus-based framework document to assist agencies in determining the cost of an EMS system²¹. The authors conducted an exhaustive literature search related to cost utility and cost analysis of EMS systems. As part of that discussion, the authors describe a framework for identifying the direct costs of an EMS system, and reported on the general paucity of information related to EMS system costing.

The authors have created a working definition of the EMS system and focused on the "EMS system as it responds to acute, unscheduled health care delivered outside the hospital within the setting of a system that deploys health resources in response to a request for emergency medical care, which includes lay responders, public safety, and EMS providers who participate in this response and the system within which they respond."

In Lerner's analysis, the author considers EMS system costs that do not include the downstream cost savings of EMS interventions, because those downstream savings are described more completely in other studies. The authors provide a comprehensive description of the resources needed to provide EMS services to a community. However, the document fails to appropriately descript the joint services component of many EMS systems. While it does briefly discuss the difficulty in allocating costs for those agencies that provide joint production capabilities, it provides no solution. This is problematic in most EMS systems because joint services are a common component—fire agencies provide multiple services, ambulances and ambulance personnel are used for both EMS and non-EMS activities, communication centers provide communications for multiple types of public safety agencies, and facilities and equipment are often used for non-EMS efforts.

C: Crosswalk with other documents and past recommendations

Institute of Medicine (IOM) Report: The Future of Emergency Care (2007). The IOM report—EMS at the Crossroads (book two of the three-book Future of Emergency Care series) is a consensus document that describes considerations for prehospital emergency medical care.

National Fire Protection Association Standard 450. NFPA 450 is a consensus guideline for EMS system design that establishes guidelines for EMS system design and focuses on 10 components of EMS systems.

EMS Performance Measures, NHTSA 2009. A collaborative project that describes standardized methods of measuring performance, some of which are specific to agencies and some generalized to broader systems.

Report on Field Experiments, National Institute of Science and Technology (NIST), US Department of Commerce, September 2010. The NIST study examines scene time savings based on the number of personnel that are deployed to typical emergency medical scenes.

D: Analysis

Though a number of studies have been conducted related to EMS services, some of which are episode of care analyses, and some of which are specific interventional analyses, there is virtually no information related to the impact of EMS system design on the outcome of patients or on the economic benefit of various types of interventions. The studies that exist consider only the most critical of patients and they often neglect the economic cost of making those interventions.

During the last five years, prominent authors published in prominent journals have universally called for additional research in EMS medical outcomes and economic outcomes. By first determining which medical interventions have the optimal impact on patient outcomes, economic research will then allow system administrators and others to prioritize design configurations to have the best opportufactors

Recommended Actions:

National Highway Traffic Safety Administration

Existing project. NEMSAC recommends that the National Highway Traffic Safety Administration continue with its existing "EMS typology" project and report back to NEMSAC on the results of the nationwide survey of EMS systems.

Future project. NEMSAC recommends that NHTSA convene an expert group of EMS professionals in an EMS summit to establish the framework for the future of an EMS Systems of the future document.

NEMSAC recommends that NHTSA embark on a project to establish an EMS Systems of the Future Document that provides guidance to EMS systems in the United States about measuring the medical and financial performance of EMS systems.

Federal Interagency Committee on EMS

¹ National Highway Traffic Safety Administration, National EMS Advisory Council, Guiding Principles and Core Issues in EMS System Design, Washington DC; December 2009

² Garvey JL, MacLeod BA, Sopko G, and Hand MM. Pre-hospital 12 lead electrocardiography programs: a call for implementation by emergency medical services systems providing advanced life support--National Heart Attack Alert Program (NHAAP) Coordinating Committee; National Heart, Lung, and Blood Institute (NHLBI); National Institutes of Health. J Am Coll Cardiol, Feb 2006; 47: 485-491

³ Quain DA, Parsons MW, Loudfoot AR, Spratt NJ, Evans MK, Russell ML, et al. Imroving access to acute stroke therapies: a controlled trial of organised pre-hospital and emergency care. Med J Aust 2008; 189:429-233.

⁴ Institute of Medicine. Future of Emergency Care: Emergency Medical Services at the Crossroads. National Academy Press; Washington, DC, 2007.

⁵ National Fire Protection Association. NFPA 450: Guide for EMS System Design. Batterymarch Park, MA., 2002

⁶ Lerner EB, Nichol G, Spaite DW, et al. A comprehensive framework for determining the cost of an emergency medical services system. Ann Emerg Med, Mar 2007; 49: 304-13

⁷ National Association of State EMS Officials (NASEMSO) and the National Association of State EMS Physicians (NAEMSP) joint position statement on EMS. Published in Prehospital and Disaster Medicine, October-November 1993.

⁸ National Highway Traffic Safety Administration, EMS Makes a Difference: Improved Clinical Outcomes and Downstream Healthcare Savings, Washington, DC; 2009

⁹ National Quality Forum, Regionalized Emergency Medical Framework, Department of Emergency Medicine University of North Carolina at Chapel Hill, 2012

¹⁰ National Association of State EMS Officials and the National Association of EMS Physicians, Emergency Medical Services Performance Measures Project: Recommended Attributes and Indicators for System/Service Performance. December 2009

¹¹ National Highway Traffic Safety Administration, EMS Performance Measures: Recommended Attributes and Indicators for System and Service Performance, December 2009.

¹² International Association Of Fire Fighters and International Association Of Fire Chiefs, EMS System Performance Measurement, 2008

¹³ Cone D, Lerner B, et al. Prehospital Care and New Models of Regionalization. Acad Emerg Med, 2010: 17, 1337-1345

¹⁴ Stiell IG,. The Ontario Prehospital Advanced Life Support (OPALS) Study. Canadian Health Services Research Foundation, February 2005

¹⁵ Block, A., National Highway Traffic Safety Administration, 2007 Motor Vehicle Occupant Safety Survey: Use of and Support for Emergency Medical Services Systems, 2007.

¹⁶ Beskind D, Keim S, et al. Risk Adjustment Measures and Outcome Measures for Prehospital Trauma Research: Recommendations from the Emergency Medical Services Outcomes Project (EMSOP). Academic Emergency Medicine, 2011, 18: 988-1000

¹⁷ National Academy of Sciences (1966). *Accidental death and disability: The neglected disease of modern society.* Washington, DC: Author.

¹⁸ U.S Department of Health and Human Services, Model Trauma System Planning and Evaluation, Health Resources and Services Administration. February 2006

¹⁹ McGlynn, EA. Identifying, Categorizing, and Evaluating Health Care Efficiency Measures. Final Report (prepared by the Southern California Evidence-based Practice Center—RAND Corporation, under Contract No. 282-00-0005-21). AHRQ Publication No. 08-0030. Rockville, MD: Agency for Healthcare Research and Quality. April 2008.

²⁰ Lerner B, Maio R, et al. Economic Value of Out-of-Hospital Emergency Care: A Structured Literature Review. Ann Emerg Med 2006 47: 515-523

²¹Lerner EB, Nichol G, Spaite DW, et al. A comprehensive framework for determining the cost of an emergency medical services system. Ann Emerg Med, Mar 2007; 49: 304-13