iProcure Security
SOLUTIONS FOR EMERGENCY MEDICAL SERVICES

Legal, Ethical and Societal
Requirements for EMS

Table of Content

Introduction

Fostering the response capacities and increasing the cooperation of the European Emergency Medical Services Systems (EMSS) is of decisive importance for strengthening resilience. In light of the multiple hazards faced by European societies, closer collaboration between public safety and health authorities on an international level is called for.

iProcureSecurity responds to the challenge of fostering effective collaboration by identifying the major issues presented by the diversity of Emergency Medical Services (EMS) ecosystems. Understanding these issues helps to stimulate R&I uptake with a focus on increasing harmonisation of operations across Europe, while delivering requirements for R&I activities to boost the development of more homogeneous EMS systems.

To enhance the response capabilities of European EMS organisations and facilitate a clear needs assessment of a major innovation procurement action, the iProcureSecurity project seeks to:

MOBILISE practitioners of emergency medical services, researchers and experts from the field to build synergies among existing actor constellations and initiate knowledge exchange.

ANALYSE the European medical emergency services ecosystem, it's capability gaps, challenges and needs, and monitor R&D initiatives to create a catalogue of innovative solutions.

ADDRESS legal issues, ethical and societal aspects that should be taken into account by the design, development and deployment of new solutions in the emergency medical field.

PROVIDE specifications about common requirements and technical tender documents for the procurement of R&D, ready-to-use by the upcoming PCP action and external procurers.

This document provides an overview of the main legal and ethical issues for people and society across five priority areas of the EMS Ecosystem which were identified during the iProcureSecurity project. Each priority area is briefly described here with a list of key questions that can guide a legal and ethical examination of proposed solutions for the EMS ecosystem. The questions are intended to draw attention to potential legal and ethical issues that might be of concern to people and society as a whole. Responses to these questions that reveal legal and ethical issues of note do not necessarily mean that the potential solutions for the EMS system are themselves problematic. Rather the questions are intended to promote considered thought and enable transparency around legal and ethical issues that in turn help inform recommendations for the development and implementation of EMS innovations.

EMS Training Needs and Requirements
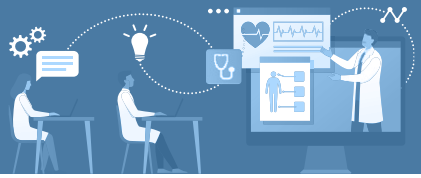
The first EMS priority needs gap identified by iProcureSecurity was EMS training. Training is expensive, time-consuming and the complexity of EMS operations mean that training is necessary for situations that include high degrees of uncertainty. EMS training equipment is expensive and real-world hands-on clinical training opportunities are limited. This can result in fewer opportunities for mentoring and feedback. This in turn can have implications for acquisition and refinement of skills.

To address these issues certain facets of EMS training can be adapted through innovative technologies and training delivery methods. One approach is to augment the training experience by increasing accessibility of ecologically valid EMS training experiences that emulate clinical hands-on conditions. In order to achieve this, innovations are needed to reduce overall cost (i.e., better quality lower-cost training simulation dummies), increase flexibility and provide trainees with increased exposure to life-like training situations and rehearsal opportunities, providing opportunities to obtain individual feedback and mentorship. Solutions could include immersive VR/AR tools. However, innovations of this nature require careful consideration of the benefits and risks, as well as of the legal and ethical implications EMS professionals, citizens and society. This prompts the following questions:

- Does this technology innovation for enhanced EMS training teach EMS workers to carry out clinical care tasks safely and effectively?

- Will the training innovations help to deliver higher quality EMS services?

- Do the technology operators and end-users have the skills and knowledge required for safe and effective use?

- Will this technology affect EMS workers wellbeing with regard to their training experience and training outcomes?

- Are there any potential misuses of this technology that may pose a threat to EMS professionals, citizens and society?

- Will societal resilience be increased through the EMS training innovations?

- Is the technology in full compliance with all regulatory directives regarding EMS training?

- Are all relevant regulatory guidelines followed?

- Are individuals' rights to privacy, freedom of information and data ownership protected?

- Are assurances provided that data will be held under the provisions of EU GDPR and all data protection and freedom of information acts that are relevant nationally?

- Is a full understanding of the knowledge base (e.g. algorithms for processing personal data) of the technology available?

- Are any elements of the EMS training innovation unknowable due to proprietary issues?
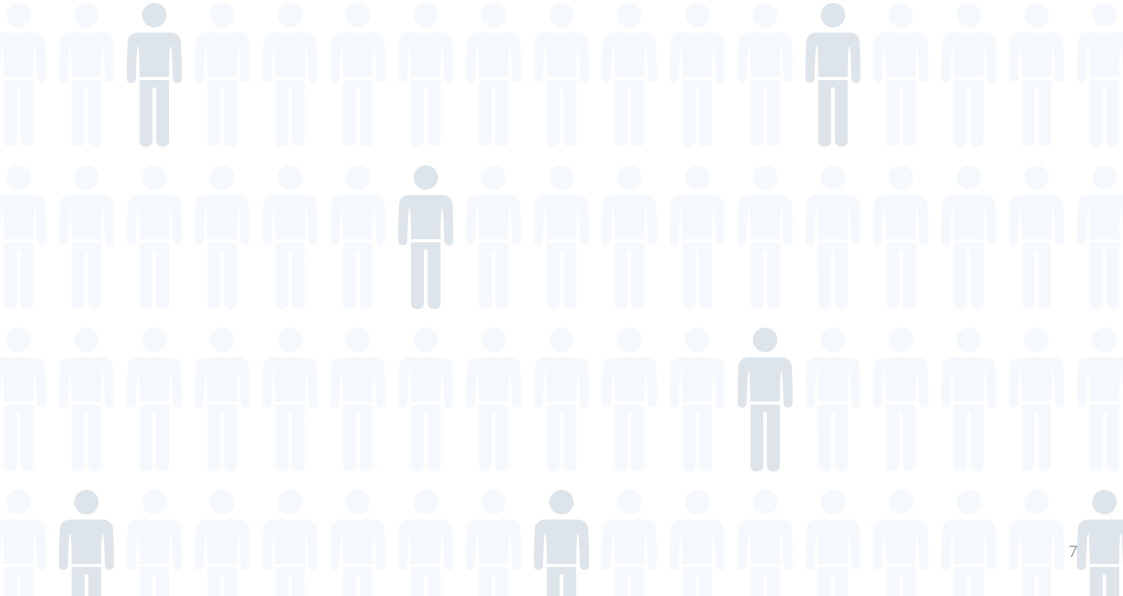
EMS Triage Needs and Requirements

The second EMS priority needs gap identified by iProcureSecurity was the triage process. This is a critical element of emergency medicine, which is employed to allocate treatment to patients according to a system of prioritization. It was reported that current triage algorithms require revision especially for large scale or complex emergency situations. There is a need for faster logistical planning, assessment of needs and response to changing circumstances. Increased access to data (e.g. patient need and in hospital availability) will: facilitate more informed treatment decisions; support better inter-operability between services; and allocate resources more effectively. It is also reported that decision support tools are lacking and current triage procedures are time consuming.

Some start technology solutions have been developed to provide electronically supported triage in mass casualty incidents. Such systems use sensors to elicit health and other data in emergency situations and communicate these data to the appropriate EMS provider. Patient and EMS providers may benefit from such solutions where they help provide quicker and improved delivery of emergency medical care. Innovations that lead to improvements in quality of clinical care provision should also result in improved clinical outcomes, which can enhance overall societal resilience. However, questions about the efficacy of such innovations in the dynamic context of triage were also raised. These concerned the potential for error in prioritization of cases during technology supported triage. This raised questions about whether risk would be mitigated or amplified.

Ethical and legal issues for triage overlap considerably with those addressed above in 'smart training'. Issues related to the ethical application of AI in decision-making are especially relevant. This is because smart triage system innovations are likely to involve the generation and harvesting of multiple-source data and its utilization by multiple end-users, in circumstances that may be chaotic and may involve collaboration between actors from a variety of agencies, including civilians. This makes data security a critical issue. It is vital that all regulatory guidance is adhered to and that issues related to the particulars of data generation and utilization in these circumstances are explored. This prompts the following questions:

- Does the EMS triage innovation provide the best care practice for each individual patient in every situation?

- Does this differ from or change current EMS triage practice? If so how?

- Does this innovation adhere to the principle of 'do no harm'?

- Does this innovation take account of the 'doctrine of double effect', where unintentional harms may result from positive treatment interventions?

- How are potential safety outcomes ascertained?

- Is the triage innovation in full compliance with all regulatory directives regarding EMS triage protocols?

- Are assurances provided that data will be held under the provisions of EU GDPR and all data protection and freedom of information acts that are relevant nationally?

- Who holds responsibility for the impacts of the smart triage system innovation (end-user, license holder, designer, programmer etc.)?

- Are individual's rights to privacy, freedom of information and data ownership protected? If so how?

EMS Treatment Context Needs and Requirements

The third EMS priority domain where needs gaps were identified by iProcureSecurity was the context of patient status and treatment setting. Problems were highlighted concerning the safety of EMS professionals as they deliver essential care services. EMS professionals can be required to deliver treatment in circumstances that involve some level of danger. Coupled with this, delivery of healthcare can be problematic when access becomes a challenge. This can be due to location, presence of hazards or resource limitations inherent in large-scale events. Time-sensitive diagnosis and treatment can be compromised when these difficulties arise. In addition, when access to a patient has been attained with difficulty, access to medical supplies and expert support from other health professionals can also become increasingly challenging.

Smart treatment solutions are envisaged as potentially making an important contribution to solving these problems. Access to information systems is considered to be a key resource. This can be realised by having access to: real time communication through audio/visual channels providing access to expertise; exchange of information and requests for medical supplies; diagnostic algorithms; and digital sensors to gather health data.

A number of e-health solutions have been developed to bridge gaps between patient, first responders and healthcare providers. Additionally, recent developments in drone technology with associated reductions in cost have made these an accessible and viable solution to medical supply issues in the field. Benefits of these innovative improvements to EMS treatment capabilities can lead to patients being stabilized more effectively in the field and hospitals that are better prepared to accept patients. Service providers can benefit from increased capabilities and reduction in mal-practice or medical misadventure events.

However, there is also a need to recognise the different technical requirements associated with delivery of care and provision of medical supplies in different environments (e.g. temperature, sterility, etc.). It is noted that there are risks that specialists could experience work overload in demanding environments. Therefore, the provision of information and other resources require consideration of the potential impact of work conditions on performance. Concerns are also noted regarding data management and use of blockchain technologies, as well as novel legal implications of on-site smart treatments.

As with all developments in the delivery of emergency medical care, careful consideration must be given to the ethical and legal implications of the innovations. Looking to the pillars of medical ethics can be helpful in providing guidance on establishing compliance with established ethical standards in the provision of medical treatment. This prompts the following questions:

- Does the treatment innovation respect the patient's right to self-determination?
  - How does it manage consent?
  - How does it establish a patient's capacity for decision making?
  - How does it manage a patient with diminished capacity for understanding (age, disability, impairment)?

- Does the treatment innovation support emergency healthcare workers' duty to 'do good' and to 'not do bad'?
  - How does the treatment innovation respond to a refusal of care?
  - How does it ascertain that the 'most-good' is done for the patient in all individual circumstances?
  - How does it ascertain that no harm will result from the treatment?

- Does the treatment innovation support the emergency healthcare worker to treat all people equally and equitably?
  - How does the treatment innovation provide for equal distribution of resources?
  - How can it account for these decisions?
  - How can it provide for equal distribution of burdens as well as benefits?
  - How can it support the upholding of laws against discrimination?

- Do these innovations give rise to any new ethical concerns?

- Do these innovations recognize that emergency medicine is prone to unpredictable situations that may bring ongoing, unique and novel ethical challenges?

- Does the treatment innovation enhance the capabilities of the organization?

- Are the benefits to the organization greater than the costs?

- If there are costs to the organization are they commensurate with the benefits to society?

- Will there be adequate resources to train workers to suitable levels of competence to utilize the new technology?

- Will overreliance on technology result in skill depletion?

- Are the challenges to data protection being adequately addressed and accounted for?

- Where safety is an issue, have issues of 'competing rights' been addressed?

- Are issues related to prejudice and stigma amplified by the innovation or encoded in the algorithms?

- Are principles of 'maximum benefit' supported by the technology?

- Are all regulatory guidelines followed?

- Are individual's rights to privacy, freedom of information and data ownership protected?

- Are assurances provided that data will be held under the provisions of EU

Bystander Engagement Needs and Requirements

The fourth EMS priority needs gaps identified by iProcureSecurity addressed bystander engagement with emergency medical situations. There are barriers for EMS to leverage bystander capabilities due to factors such as: lack of first aid training for citizens; bystander uncertainty due to lack of knowledge and support; and fear of causing harm or injury either to patients or oneself. While 'Good Samaritan' clauses exist in law, significant concern regarding legal liability remains.

There is a need for bystanders to be supported on site with fast connection to EMS dispatch centres to access medical information and expertise, and other first responder knowledge. This could be facilitated by a system that has the capability to manage emergencies, identify the location of the victim and identify support for bystander response. Such a system could be configured offer real time audio/visual communication between hospital-based or other medical experts, who could respond to visual information and give step-by-step instructions where needed. A bystander support system could also benefit from rapid access to nearby resources (e.g. AED) and other trained volunteers in the vicinity of an incident who are available to be mobilized in response to need.

There are projects in development and systems that are targeting many of these needs (e.g. GoodSAM, NEXES and EVapp). The benefits of approaches such as these are potentially very significant. Targeted solutions can lead to improvements in care through decreased response times and earlier delivery of treatment by members of the public. Innovations can help improve bystander confidence and motivation, increasing the likelihood of engagement with an emergency situation. Solutions can also help provide timely response to help meet the needs of vulnerable or disabled people who may be at higher risk of adverse health outcomes. In addition, mobilizing citizens to provide interim support in emergency situations can help build community solidarity and positively impact on societal resilience.

However, such solutions may also pose risks. A significant risk identified is the current lack of flexible and up to date laws to govern first aiders, volunteers and active bystanders. The behaviour of people can be significantly affected when ethical conflicts can arise where legal directives are ambiguous, non-specific or overly rigid. In addition, clinical issues could be a factor where bystanders or volunteers may not, for various reasons (e.g. panic and stress), have the capacity to follow instruction to an adequate standard.

Therefore, innovative solutions for bystander intervention in EMS incidents are likely give rise to significant legal and ethical issues that need to be addressed. The following list of questions is useful in this context to examine concerns:

- Do the bystander mobilization innovations recognize that emergency medicine is prone to unpredictable situations that may bring ongoing, unique and novel ethical challenges?

- What systems do the innovations have in place to manage these challenges?

- Do the bystander mobilization innovations address ethical conflicts and concerns that may arise, such as competing interest (e.g. multiple casualties, personal safety)?

- Do the bystander mobilization innovations address ethical issues related to competency (cognitive challenges, emotional response to incident)?

- How will EMS innovations address personal distress experienced by bystanders?

- How will EMS innovations support bystanders in upholding the principles of medical care delivery (non-maleficence and beneficence)?

- Will societal trust in EMS be increased though an increased bystander response cohort?

- Will citizens have increased or decreased motivation to engage with emergency situations in a helpful way?

- Will more citizens volunteer to take first-aid training?

- Where does legal responsibility lie if a bystander is given wrong direction or follows direction incorrectly?

- Are adequate legal protections in place for bystanders where problems arise but bystanders have acted in good faith?

- Are there adequate legal protections for data collected in the environment of the accident without permissions?

- Do the bystander mobilization innovations include adequate protocols for the management and protections of video images collected?

- Are individual's rights to privacy, freedom of information and data ownership protected?

- Are all regulatory guidelines followed?

- Are assurances provided that data will be held under the provisions of EU GDPR and all data protection and freedom of information acts that are relevant nationally?

Emergency Medical Communications Centre

The fifth EMS priority needs gap identified by iProcureSecurity addressed Emergency Medical Communications Centres (EMCC). There are several challenges that are faced by EMCC operations including: eliciting correct and useful information on the emergency event; establishing the location of the emergency incident; identifying the appropriate resources to send to an emergency; the number of real versus fake or error calls; communication and language barriers; capacity limitations in surge events, etc. These difficulties can lead to delays in recognizing and prioritizing patient needs as well as to deploying adequate resources. In addition, capacity limitations can have negative implications for providing adequate service for larger scale incidents.

A system is required that addresses EMCC capacity and limitations. A number of projects could present solutions to help meet these needs (e.g. NEXES, AI4EMS). Innovative solutions could be used to access data to accurately identify incident locations and certain specific conditions (e.g. cardiac arrest). Such innovations may use AI and blockchain technology to facilitate the aggregation of data. Algorithms that can address language and communication barriers could reduce or even remove the need for foreign language translators. Data integration tools could help inform the optimal allocation of resources to emergency events.

Benefits to society from these and other innovations could be considerable. Improving EMCC services could increase the speed and efficiency of responder deployment, facilitate callers with communication barriers and assist dispatchers in directing services to incident scenes with greater accuracy and flexibility. The system could offer benefits to casualties and bystanders with additional needs, thus improving in quality of care and health outcomes.

Emergent risks from the development of innovative solutions for EMCC are also notable.   Primary among these is the concern that clinical mistakes could occur through automation of call filtering and prioritisation. The potential adverse outcomes of this could result in calls being mislabelled as 'fake' or 'low priority' when in fact they were genuine pleas for help or in situations where the wrong prioritization of cases led to a misallocation of resources. In addition, there was uncertainty around the legal and ethical factors involved with use of the 'blockchain' technologies that are a feature of some of these innovations.

There is a need for clear and knowable decision-making algorithms as well as clearly defined protocols to ensure competent use of new EMCC systems. This also implies the need for protections for EMCC personnel and the public, in regard to data use and ownership. Consequently, adoption of innovations for EMCC requires careful examination of questions regarding ethical and legal implications, including:

- Has a legal basis for prioritization of resource allocations been established?

- Are decisions regarding the prioritization of resource allocations clear and knowable?

- Have issues of legal culpability and liability been explored (i.e., if inappropriate resources were deployed)?

- Are systems in place to mitigate the risk of mistaken labelling of fake calls?

- Does the system promote increased trust and acceptability?

- Are learning systems embedded in the innovation, facilitating organizational learning from mistakes?

- Do improvements in functionality increase worker morale and motivation?

- Do changes in the EMCC system create an acceptable level of burden for individuals?

- Do changes in the EMCC system encouraging citizens to work collaboratively with EMS?

- Do changes in the EMCC system support increased bystander engagement?

- Do changes in the EMCC system effectively support the rights of all individuals equally?

- How is ownership of any aggregate data tracked when it is absorbed by the EMS ecosystem?

- Is data autonomy supported, at what point does the individual lose control of their data?

- Does the individual retain ownership of any aggregated data created?

- Are systems in place to verify the safety and security of data?

- How will the individual's rights to freedom and dignity be protected (i.e., casualties remaining anonymous at a high-profile incident)?

- Have future issues regarding the monetizing of data been explored (i.e., if value was identified in data that could be used for research)?

- Are assurances provided that data will be held under the provisions of EU GDPR and all data protection and freedom of information acts that are relevant nationally?

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🖥 www.iprocuresecurity.eu

✉ office@iprocuresecurity.eu

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