

GUIDELINES METHODOLOGY

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EXECUTIVE SUMMARY

In this Deliverable the methodology for the development of the ERMG is defined. A step-wise approach is suggested, mainly consisting of the following steps:

- Planning the guidelines
- Information collection and review
- Guidelines formulation
- Review of guidelines
- Implementation and impact evaluation
- Further actions

These steps are described in detail within the Chapters 3 to 8 in the present document. Chapter 1 provides an introduction, while Chapter 2 discusses guidelines methodologies in general. Finally, in Chapter 9, conclusions are drawn.

This document is expected to set the general framework of the work to be undertaken within WP3, in terms of defining ERMG and adapting them to the Urban Transport System environment, for testing and verification.

PROJECT CONTEXT

Workpackage	WP3 ERMG
Task	T3.2: Guidelines Methodology
Dependencies	These guidelines influence the whole project work.

Contributors and Reviewers

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1 INTRODUCTION

For the needs of the European Resilience Management Guidelines (ERMG) that are being developed within RESOLUTE, there is the need to define from the very start a concise methodology that is going to be followed throughout the process. To this scope, generic methodologies for guidelines development are going to be taken into account, in order to follow a widely applied and approved process. Moreover, the already issued by the EC Staff Working Paper *"Risk Assessment and Mapping Guidelines for Disaster Management"* is going to be taken into account, in order to be in accordance with the EC expectations.

Thus, in the present Deliverable the main steps to be followed during the development of the ERMG are going to be defined and analysed, as a result of the work performed in T3.3. Following this analysis, the rest of the WP3 Tasks will proceed in the actual development of the guideline, according to the steps defined in D3.4.

2 ABOUT GUIDELINES METHODOLOGIES – A STEP-BY-STEP APPROACH

There are two key principles to rigorous guidelines development

- 1. Systematic development methods which search, appraise, extract and review the data as objectively as possible.
- 2. Transparent documentation of processes and decisions so that the reader can understand why the guidelines comes to the conclusions they do.

The development of new guidelines should, in principle, include the following stages:

- <u>Planning</u> including scoping the topic, drafting a project plan, funding and forming a Guidelines Development Group (GDG).
- <u>Development</u> including searching and reviewing the data, holding GDG meeting to review data and formulate recommendations and writing the guideline.
- Validation including peer reviewing the guidelines.
- Implementation and impact assessment including developing tools that will help using the guidelines.

3 PLANNING THE GUIDELINES

The first thing to do, before starting the definition of the guidelines, is to consider a number of questions that need to be answered. This will specify what will (and will not) be included in the guidelines to be produced and it should be done from the very beginning for several reasons. Apart from being helpful in terms of focusing in the right topics, it also serves as a tool for avoiding misunderstandings at later stages, as well as preventing from unnecessary widening of the contents of the guidelines.

The first and basic question to be answered is: *What is the need that led to the development of these guidelines?* Who is asking for this guideline, what is the need that it will serve, why the specific timing is crucial, etc are some of the issues to be considered in order to answer this question.

Apart from the basic question, the following ones should also be considered before starting the development of the guidelines.

- What would be the benefits that will result from the publication of these guidelines?
- Are there other relevant existing guidelines in the same topic?
- Is there any relevant standard to which the guidelines have to conform in terms of their structure and formalization ?
- Which is the dictionary of terms that would be surely used into the guideline? How are they defined?
- What is the target audience for these guidelines?
- What areas of the topic will and will not be covered?
- What is the time horizon for completing the guideline?
- What are the available resources?
- What existing information can be useful?
- Which kind of existing data can be useful?
- Who should be consulted and involved?
- What will be the format of the guideline?

These issues should be clearly answered and decided in order to proceed with the actual development. This will prevent the process from shifting from the right direction and will facilitate the work.

3.1 Defining the scope of the guidelines

A fundamental step in the process of defining the guidelines is to decide and clearly state its scope. This mainly involves the definition of the content, the questions to be answered and the related recommendations. In order to define the scope of the guidelines, there are some suggested steps to be followed:

- a) Set up a group for the definition of the scope, including representatives of different WPs and related actors
- b) Make a list of the priority topics for the guideline. In this, there should be focus on the issues that would result in radical changes or interventions in current practice, as well as considering the feasibility of the resulting recommendations.
- c) Make a list of the expected recommendations (if known)
- d) Based on the above, the questions to be answered should be defined. These questions will guide the data synthesis
- e) Once the scope has been agreed by the group, it should be communicated to the Consortium and the ERMG Advisory Stakeholder Board for comments/additions/approval.
- f) Finally, a reality check should be performed, in terms of whether the scope is feasible as such, as well as within the time and money restrictions.

It is also useful to decide, at this early stage, whether the guidelines to be formulated will need to be updated, in which time frame and/or under which conditions, etc.

In the specific case of the guidelines to be produced within RESOLUTE, the process is twofold. On one hand generic guidelines are to be produced, applicable in any case of resilience management and on the other, these should be specified and operationalised for the Urban Transport System in particular, in order to be tested and verified in the project pilot tests. This should be kept in mind throughout the guidelines development process and mainly when defining the scope and the list of questions to be answered by the guidelines.

3.2 Guideline development group (GDG)

It is at principle necessary to have a group of related experts advising on the content of the guideline. This group should at least develop and agree on the guidelines produced and review the final outcomes. Within RESOLUTE this group has been foreseen since the proposal stage and is the ERMG Advisory Stakeholder Group and RESOLUTE User Forum, managed in T3.1, in cooperation of course with the RESOLUTE Consortium. The group communication and coordination is mainly performed electronically (through emails and web-meetings), however a number of physical meetings will also be necessary.

The main responsibilities of this group can be summarized in the following:

- Advise on the priority of questions and scope of the guidelines
- Advise on the choice of important outcomes for decision-making
- Comment on the data and evidence used in the formulation of the guidelines
- Advice on the interpretation of data and evidence with focus on the balance of risks and benefits
- Contribution in guidelines formulation and final review of outcomes.

The composition of the group and the distribution of roles and responsibilities are crucial in order to achieve a functional and effective workflow. The group should be multidisciplinary, including experts from related sectors of critical infrastructure, as well as resilience specialists (ERMG Advisory Stakeholders Group), as well as users' and stakeholder groups' representatives (RESOLUTE User Forum) and – of course – RESOLUTE partners. The group chair and the roles of its members will be further defined in T3.1. In principle, the RESOLUTE WP3 partners will be responsible for actually writing the guidelines, while the other two bodies will have an advisory, commenting, guiding and consulting role. Of course, in case that in the course of development of the guidelines there raises the need of including additional experts, or consulting a specific authority etc., the Guidelines Development Group will have the freedom to act as seen best for the optimal benefit of the work.

3.3 **Definition of questions and choice of outcomes**

The development group starts with the definition of the questions that should be addressed through the guidelines to be produced. These questions are of utmost importance, as they should be carefully formulated in order to guide the research and analysis towards the desired and adequate direction, according to the scope of the guidelines. Their selection directly affects the scope of the guidelines and drives the direction (inclusion/exclusion of data) as well as defines the type of information that will be collected and assessed. At the same time, these questions serve also as a starting point for the formulation of the guidelines. Thus, it is very important that they are clear and concise, not allowing for possible misunderstandings that may lead to unnecessary excess work.

It is usually helpful to divide the questions in different categories, such as:

- Definitions/background questions, e.g. What is resilience?
- Facts/foreground questions, e.g. What measures improve resilience?
- Recommendation/decision, e.g. Should measure X be applied in the case of fire?

The questions to be covered should be identified based on the needs of the affected technical and/or policy needs and relevant input from the related stakeholders and experts. Additional input from the actual users (facilitated through the User Forum) is also useful, providing an extra insight. In principle, the questions should focus on topics of controversy that need to be answered by the guidelines, on topics where no prior experience exists, as well as on topics where there is a need for change in policy or applied practice.

To facilitate the questions' development procedure, the GDG can organise its work in the following steps:

- Specification of the purpose of the guidelines
- Drafting foreground and background questions as researchable questions
- Prioritisation of questions
- Determination of the questions that may need systematic reviews throughout the process

The last part will most probably define also the time and resources needs for the completion of the guidelines formulation process.

The list of questions is expected to be long, in order to cover the wide range of factors that are associated with resilience management. Some generic examples could be the following:

- What phenomena are associated with resilience management?
- What is the frequency of cases where resilience management is needed?
- What are the causes of the problems that need resilience management procedures to be applied?
- What happens when such a problem occurs?
- Where has such problems occurred?
- How can resilience management be applied? (by which measures)
- What policies can be introduced in order to alleviate resilience management?
- What kinds of behaviours are expected by the general public in case of problems occurrence?
- How can these behaviours be addressed by e.g. awareness campaigns to reduce risk?
- What long-term issues could be caused by wrong/unpredictable/uncontrollable behaviours by the general public?

Of course this kind of questions will be formulated into more detailed and specific ones, i.e. into questions that their answer should come from the guidelines to be developed.

The questions typology will at large determine also the typology of data that will need to be collected (quantitative, qualitative, data from tests with users, research outcomes, existing practices, etc.).

Upon consensus of the core group on the list of questions, these should be communicated to the wider group of experts and related stakeholders (members of the ERMG Advisory Group, User Forum and beyond) for comments and revisions. The aim should be to identify gaps in the questions' list on crucial issues that should be included in the guidelines and/or modifications in the already proposed ones.

4 INFORMATION COLLECTION AND LITERATURE REVIEW

In this step the actual collection of data, experience, implementation examples, etc. that should be studied, assessed, prioritised and, consecutively, lead to the synthesis of the first draft of the guidelines takes place.

A specific protocol should be defined, clearly stating the criteria and methods to be used. The assessment should be performed in terms not only of relativeness but also of quality, cost-effectiveness, applicability, etc.

It is of utmost importance to include data (or at least indications) related to the actual consequences of the application of the proposed guidelines.

It is most preferable to implement this work by the form of a systematic, rather than a narrative review, i.e. addressing a specific research question and applying a robust scientific approach towards the selection,

assessment and synthesis of relevant existing data. For this purpose, a protocol is needed which would specify the following:

- Search strategy used for identification of existing information
- Eligibility criteria for selection of information
- Quality appraisal process
- Methodology for the synthesis of results and (optimally) quantitative synthesis of the results of studies to estimate the overall effect of a measure (meta-analysis)

In the course of retrieving and assessing data, one should prioritise the questions or issues (as in the definition of scope) on which the data collection process should focus.

4.1 Information retrieval

4.1.1 Existing systematic reviews

Existing reviews should be used wherever possible and should be updated if necessary. The first step in data retrieval is to identify relevant systematic reviews for each of the selected questions. Before starting a major process of data retrieval the guidelines, it is suggested to first search for existing guidelines. If they are of reasonable quality, they should have lists of references, including systematic reviews, which can be used to assist in the search. Systematic reviews can include all types of study design, allowing to select the most relevant to answer the list of questions selected.

The search strategy should be well documented and should specify:

- the details of the databases (including web sites) to be searched, and the search strategy to be applied to each database;
- the details of each strategy as actually performed, with the date on which the search was conducted and/or updated

4.1.2 Adequacy of systematic reviews

Once the reviews are retrieved, they should be checked for:

- relevance (to the questions to be addressed in the recommendations);
- timeliness (assessed by date of last update);
- quality (assessed by a standard critical appraisal instrument).

If there are several relevant systematic reviews, it is advisable to use the most recent one of high quality. If the identified systematic reviews are all of low quality, then it would be better to perform a new one. If a review is of high quality but more than two years old, it is advisable to update the review to include more recent data.

4.2 **Commissioning systematic reviews**

A new systematic review is needed if:

- there are key questions to be covered in the guideline that are not answered by an existing systematic review;
- the only relevant and high-quality systematic review is over two years old.

Preparing systematic reviews is time-consuming and requires technical capacity and resources. It is suggested that this should be done only if there is a specific reason for doing so and time and resources are available. Systematic reviews used in guidelines must be of high quality and should be guided by relevant standards.

4.3 Conducting a systematic literature review and search

Conducting a systematic literature search is a complex and time-consuming task. It would be useful to also consult an information retrieval specialist. Important decisions need to be made about the databases to be searched and the search strategy to apply.

Generally, the search strategy is guided by the elements of the research question and the types of studies that are researched. Major Journals (such as Transportation Research, Safety Science, Journal of Applied Psychology, Nature, International Journal of Disaster Risk Reduction, etc) and databases should be the priority targets of the search, as well as already performed research projects' results. Of course websites can also provide useful input. It is important to scan key web sites individually as general search engines do not retrieve all the relevant information on a web site. The combination of efficient use of search engines and targeted web sites and authors is much more effective for identifying unique information than large unfocused searches. Personal contact with key experts will help identify sources of information not found in the published journals or cited on web sites.

In the final guideline document, a summary of the key elements of the systematic review should be provided together with links and references. The summary may include details of the search terms used and the date on which the search was conducted and/or updated.

4.4 Information retrieval for compilations of recommendations

Guidelines can also be developed on the basis of existing recommendations, the selection of which should be done in a systematic and transparent way, similar to the process described above.

The protocol should describe:

- the search strategy used to retrieve existing guidelines;
- how the relevance and quality of guidelines and their underlying data will be assessed;
- how the selection of guidelines will be made if there are more than one on a given topic;
- how to proceed if no guideline on a question of relevance to the compilation is found (a systematic retrieval process for existing reviews or primary studies should be considered, as above).

4.4.1 Information assessment

Assessing the information that has been retrieved is a crucial step that enables the guidelines development group to formulate recommendations. This assessment is based on the systematic review(s) you have done or commissioned. From these review(s), data summaries must be prepared for the guideline development group.

If the data retrieval has identified systematic reviews as the basis for developing recommendations, data summaries (or profiles) should be created, as a structured and transparent assessment of the quality of data. If there is more than one high-quality, relevant and up-to-date systematic review, the best one would serve as a starting point and will be supplemented as needed with additional data from the systematic reviews that meet the selection criteria determined previously.

5 GUIDELINES FORMULATION PROCESS

For the formulation of guidelines, the GDG should meet and discuss to reach consent on the final guidelines to be issued.

For each of the guidelines, the quality of data should be made clear. Guidelines should specify the perspective that is taken (e.g. stakeholders, society, etc.) and which outcomes were considered (including which, if any, costs). The language used in guidelines should be clear and direct, indicating clear actions. Where possible, the language should be consistent across guidelines (e.g. in cases where an action is unquestionable the word "should" to be used).

The difference between a data review and a guideline is that a guideline distils the data and makes recommendations for practice. The recommendations are developed by the Guideline Development Group. They should consider the data presented in the data reviews (including the benefits, side effects and risks), applied existing practice and users' preferences.

Guidelines should be

- clearly presented and unambiguous
- provide guidance on what to do in a given set of circumstances
- state alternative actions or reaction options where relevant
- validated by reference to the strengths and limitations of the data that supports it

Guidelines are usually a mix of data and expertise. It is important, where good data exists, that the guidelines are based on this. However, frequently there is little or no data to underpin common sense or 'barn-door' standard practice, which may be helpful advice to include in the guideline.

Even when data is available the decisions may not be clear-cut. In some cases the harms and benefits of an investigation or intervention will need to be debated. The balance may be different for different cases (e.g. different types of infrastructure or affected stakeholder/users groups). If benefits only marginally outweigh harms, the cost of implementation will also be a consideration for the GDG even in the absence of formal economic analysis.

A specific template for the outlook of the final guidelines should be defined and followed. This should be structured according to the defined scope of the guidelines and the questions that have been selected. It would include all the parameters that are relevant to the guideline. Such a template will be further refined within the work of WP3.

5.1 How the guideline development group decides on guidelines

The Guideline Development Group (GDG) will meet on a number of occasions during the development of the guidelines. Its responsibilities include:

- reviewing the scope and ensuring that nothing crucial has been omitted within the resources available
- agreeing the key questions, within the scope,
- reviewing and debating the evidence
- writing guidelines
- considering peer review comments

5.1.1 The Role of a chair

A GDG chair should be seen to be unbiased and have the respect of the GDG. The chair does not need to be an expert in the topic. It is often better if the chair is a generalist who understands the problem without having strong views on what the guidelines should recommend.

The chair's responsibilities include:

- effective chairing to the timetable and agenda
- facilitating constructive discussion where all GDG members are able to express their views
- summarizing the main points of the discussion and moving the GDG toward a decision if at all possible.
- balancing evidence and expert advice in the formulation of a cohesive set of guidelines

5.1.2 Planning Meetings

The number of meetings will be determined by the size of the scope and the feasibility of meeting. If the number of meetings is limited, developers should consider on-line meetings or tele-conferences between face-to-face meetings to ensure that the GDG is up to speed and the work progresses. In any case, it is best to plan meeting dates well in advance to ensure good attendance. As it is important that members prepare for the meetings, the papers should be sent out at least a week in advance.

At the first meeting, it is helpful to establish some rules for how the GDG will operate. This may include:

- What is the quorum for decision-making?
- If a member is unable to attend should they send a substitute?
- Are the meeting papers and the guideline draft confidential?
- How will responsibilities be allocated amongst members?
- What are GDG member's rights to the material?
- Who will be authors of any publications?

5.1.3 Reaching a decision

Ideally the group should decide on the final guidelines based on consensus. Consensus does not necessarily mean unanimity, however, and in some cases a vote may need to be taken. The group should discuss and agree on the process at the beginning of the meeting.

It is most effective if the group considers draft guidelines that have been prepared by the writing team. A suggested process is as follows:

- the draft guidelines are presented by the writing team, with a justification and reference to the relevant data summary;
- the data is reviewed and discussed by the group,
- a first set of guidelines is agreed;
- the group considers costs, values and preferences;
- if necessary, the first set of guidelines is modified;
- final agreement on the guidelines is reached.

5.1.4 Writing the guidelines

The guideline should provide guidance but should also document its development so that the reader can be confident about the method of development. The guideline should generally include:

- Abstract
- Dictionary of definition
- Introduction to include the need for the guidelines and background facts
- Methodology briefly describe the methodology that has been followed for formulating the guidelines
- Data Review a review, appraisal and distillation of the data for each question.
- Actions include the recommended actions for each of the questions and information of how they were derived.
- Limitations of the guidelines including the strength of the data and areas of uncertainty, how benefits and harms were balanced in formulating the guidelines, the applicability to different affected groups and types of infrastructure and any potential biases in the conclusions or recommendations
- Examples of implementation and audit tools
- Review Date

6 REVIEW OF GUIDELINES

6.1 **The peer review process**

The ERMG guidelines should undergo peer review during development and before the draft is finalized. There are several stages at which peer review should be applied:

- Drafts of the questions formulated for the guidelines should be circulated for comments to experts and end users (mainly through the ERMG Advisory Group and the User Forum).
- If systematic reviews are undertaken or commissioned, the systematic review protocol (outlining search strategy and eligibility criteria) and included studies may be circulated to experts for comments on the methods and data identified.
- Drafts of data profiles and tables should be circulated to experts for identification of any missing data.
- Before the meeting, a draft of the guidelines document should be circulated widely for comment by experts and organizations representative of the relevant stakeholders.

The process of reviewing comments and responding to them should be transparent. It is not necessary to respond to every single comment individually; this should be made clear at the beginning of the process. However, an "audit trail" should be drawn up to show how comments were handled, either as a version of the document with the changes, or as a separate summary.

If the guidelines document is circulated for comments after being finalized, it should be clear what kind of changes can still be made. It is suggested that changes after finalization should be restricted to major errors of fact.

7 IMPLEMENTATION AND IMPACT EVALUATION

7.1 Implementation

Implementation guidelines should be taken into account right from the beginning of development. It is essential to decide on the desired outcome of implementation.

The basic steps for implementing a guideline are:

- Analyse local needs and priorities (look for additional data on actual practice).

- Identify all potential barriers and facilitating factors.
- Determine available resources.
- Design a strategy to support the adoption of the recommendations and to make the overall context favourable to the proposed changes.

In the case of ERMG and especially their operationalisation for the UTS, a first implementation, mainly for validation and evaluation purposes, will be performed within the RESOLUTE project, by means of developing dedicated tools and testing them in real life environments (the RESOLUTE pilots in Florence and Athens).

7.2 Validation and impact evaluation

In order to validate and evaluate the impact of the proposed ERMG (and especially their operationalisation for the UTS) within RESOLUTE it is foreseen to implement dedicated tools (such as the CRAMSS) following the content of the guidelines, which will be tested and evaluated in real life environments, i.e. the two RESOLUTE test sites in Florence and Athens.

For this reason, specific test scenarios will be defined, in order to demonstrate the functionalities of the CRAMSS, along with a common framework for the evaluation (within D6.1), including:

- Evaluation criteria
- Data gathering and analysis tools
- Indicators to define the confidence levels of pilot results
- Usability issues for the involved users
- CBA/CEA issues and market visibility
- Thresholds to estimate safety impact
- Evaluation tools to be commonly used for both sites

The findings of this process will feed back to the ERMG development task, for update and improvement of the proposed guidelines.

8 FURTHER STEPS

Upon the finalisation of all the above step-wise procedure, including the impact evaluation of the proposed guidelines, there are several further actions that can be proposed in terms of the future of these guidelines. It is usually helpful to setup a roadmap, taking into account the expected progress in the area and striving to make future projections, in different time-frames, for the situation in resilience management (in our case). Identification of further research needed in the field is a valuable task in this process, showcasing the topics of research where currently not much has been done and whose outcomes may radically change (optimally improve) resilience management.

Taking the above into account, and within the overall roadmap, plans for further updates of the issued guidelines can be proposed, along with the timeframes in which these updates would be mostly beneficial.

9 CONCLUSIONS

In this Deliverable, the methodological steps needed in order to define the ERMG are presented. These will be put in practice within WP3. Formulating guidelines is a rather complicated process which is structured in a stepby-step mode here for facilitating the application of the methodology. As pointed out also in the previous sections, there should be particular emphasis in the retrieval and assessment of data, as this will form the basis for the final guidelines to be produced. Especially in the case of operational data retrieval, strong commitment of the data owners in the process of data management should be secured with the respective organisations. Moreover, also within the operationalisation phase of the guidelines, issues regarding the cooperation, orchestration and transparent exchange of data within and between organisations (such as local authorities, security bodies, etc.) should be clearly defined, as their interaction is crucial in terms of resilience management and risk prevention in a city. These and many other specific issues will come up during the application of the suggested methodology.

Last but not least, the contribution of the rest of the work taking place simultaneously within the project (e.g. in WP2, in the pilot sites, etc.) is also of utmost importance for the optimal outcome of the guidelines development process.

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