

Mutual Learning Exercise (MLE) on Research Integrity

Training and Education

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Challenge paper No 4

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1 INTRODUCTION

On July 10th 2018, representatives of 13 participating countries met in a Scoping Workshop for the Mutual Learning Exercise (MLE) on Research Integrity (RI) and agreed on four priority topics:

- 1. Processes and structures for RI*
- 2. Incentives for RI*
- 3. Dialogue and communication about RI*
- 4. Training and education for RI*

This Challenge Paper addresses the fourth priority topic - training and education for RI – with the aim of helping MLE participants prepare for the third and final Working Meeting that will take place in Paris, FR, on the 14th of May 2019. The overall scope of this topic was defined in the Kick-off Meeting that took place on the 14th of November 2018 in Brussels, where representatives of all the 14 participating countries (Austria, Bulgaria, Denmark, Estonia, Finland, France, Greece, Ireland, Lithuania, Luxembourg, Moldova, Norway, Spain, and Sweden) shared information about RI frameworks in their countries and discussed their learning objectives.

2 SCOPE

During the Kickoff meeting, participants manifested an interest in sharing and comparing experiences about providing instruction on research integrity. In particular, it was determined that the objectives that are of most immediate and relevant interest to participants were the following:

- 1) To compare training programs on research integrity, with regards to aspects including:
 - a. Objectives, content and structure of the courses
 - b. Mode of delivery, i.e. whether online or in-person
 - c. Assessment of the courses, whether in the form of feedback from course participants, or a test of the knowledge acquired during the course, or as a study on changes in the beliefs and behaviour of participants
- 2) To share successful and unsuccessful experiences about different aspects of training, such as:
 - a. Mode of course delivery: online training modules, vs in person teaching, versus role playing and other interactive approaches
 - b. Incentives for the course, e.g. making the training mandatory rather than optional, and how to make it more interesting and fun for participants
 - c. Career level and occupation of participants: from undergraduate students to senior-level lab leaders or even administrative staff and policy makers

Furthermore, two overarching objectives were anticipated to be of general interests.

- 3) To determine if and how each of the elements of RI training listed above needed to be tailored to the specific needs of a research field, a particular country or even a particular institution

- 4) If and to what extent course material could be shared across countries, and in particular whether a repository of anonymized real cases of science misconduct or other ethical breaches could be created to provide instructional material for RI education across the EU.

In order to provide a scholarly accurate empirical and theoretical context for the discussion to be had at the Working Meeting, this Challenge paper will present a review of the relevant literature.

The research literature on education in research integrity and research ethics more generally is enormously rich, and conducting a detailed analysis of any particular issue pertaining to the research questions posed by the MLE would be beyond the scope of the MLE challenge paper. Therefore, the challenge paper will primarily refer to recent secondary literature. In the "Lessons" section, in particular, it will review and then summarize relevant conclusions of recent systematic reviews, meta-analyses and other secondary analyses of empirical studies.

Most of the current literature on research integrity (RI) education originates from the United States, where policies to implement interventions to prevent research misconduct (RM) and promote RI started to be deployed in the 1980s, and active programs of training for NIH-funded (biomedical) research have been a requirement to research institutions since the 1990s¹. Therefore, whereas the objective of this report is to draw lessons that are relevant to the future of RI instruction in EU countries, the main source of research evidence on the nature and effectiveness of RCR instruction will be literature authored by US scholars and derived from the experience with researchers and students in the US. Establishing if and to what extent these results are relevant to the European context is a research question in and of itself, and will require the production of empirical evidence, the lack of which will be identified as one of the challenges emerging from this report.

3 LANDSCAPE

3.1 Definition of the problems:

3.1.1 Course content and objectives

Who needs teaching in RI?

Most policies, initiatives and academic studies on RI education focus on young researcher, the training of which is most typically and generally defined as training in the "Responsible Conduct of Research" (RCR). However, virtually all other professional figures that play a role in the scientific and research system could benefit from training in aspects of RI that are relevant to their work.

Research and academic administrators, for example are called to make appropriate ethical decisions and would benefit from training that enabled them not just to become versed in all relevant policies, but also to recognize situations that may present ethical conflicts, to know who to consult for help and advice, and to know how to implement the best solutions to ethical conflicts².

Journal editors and/or peer-reviewers are another category that has been often suggested to require dedicated training. As argued by the authors of a systematic review on the effectiveness of such training, for example, "One reason for bias in reporting and the problem of unusable reports could be [...] that the peer review process for journal publication has serious flaws, including possibly being ineffective, and having poorly trained and poorly motivated reviewers. Similarly, many journal editors have limited knowledge related to publication ethics. This can ultimately have a negative impact on the healthcare system."³

Training in recognizing and addressing relevant ethical and integrity issues is also likely to benefit individuals who manage research funding, as well as Research Integrity Officers themselves.

Connected to the question of who should receive training is that of when, in other words, whether training in RI ought to constitute a training for "young" and "inexperienced" actors,

or whether mid-career and senior figures would benefit from receiving specific training for the first time or perhaps on a continuing basis, as part of one's professional development.

This report will still mainly have to put most emphasis on RCR training for early-career researchers, because this is still the main concern and is what most experiences and literature has been devoted so far

What should be taught in a RI course?

Just as there are multiple different actors that can benefit from RI courses, there are multiple areas of integrity, ethics and practice that such courses can convey

An early standard, set by the RCR program of ORI, in the USA, includes nine main areas⁴:

1. research misconduct
2. protection of human subjects
3. welfare of laboratory animals
4. conflicts of interest
5. data management practices
6. mentor and trainee responsibilities
7. collaborative research
8. authorship and publication
9. peer review

The list, however, could be much longer, and documents in the US and EU have indeed often presented a more extensive list. The recent Science Europe Survey Report on Research Integrity, for example, lists the following recommended training objectives⁵:

- 1) Research planning and conduct of research: research design, methodology, analysis etc. (including unconscious bias)
- 2) Data management: lab tools, data acquisition, record keeping, data sharing and ownership, data storage etc.
- 3) Responsible authorship and publication: rules of authorship, scientific writing, referencing, how to use and value internet resources etc.
- 4) Mentor/mentee relationships
- 5) Collaborative research, responsibilities of researchers, students, institutions etc.
- 6) Conflicts of interest
- 7) Definitions of and differences between questionable (and unacceptable) research practices and research misconduct: policies for handling allegations, where to go in case of conflicts in research integrity and misconduct issues

In addition, the report suggests, for more experienced researchers:

- 8) Peer Review
- 9) Ethical issues pertaining to research with human participants
- 10) Ethical issues pertaining to research with animals
- 11) Ethical issues of dual use research
- 12) Social responsibility, environmental and social impacts of research

The list could easily be extended further, to include, for example, modules on:

- How to foster and promote RI, aimed at institutional leaders and administrators
- How to teach RI (e.g. train the trainers)
- How to coach on RI
- Principle and practices of Open Science.

The latter topic, Open Science, deserves particular attention, because it is very rapidly growing in importance. It is also a topic that is very closely intertwined with RI and RCR, because sharing data and methods is a complex ethical issue and because transparency in reporting and other forms of open and frank communication are pivotal means to prevent and correct problems with the scientific literature.

A good example of the topics that a course in open science could include is offered by The Open Science MOOC (Massive Open Online Course, opencourseware.org), which is a leading platform of the Open Science movement. Currently in development, the course lists ten modules:

- Open Principles
- Open Collaboration
- Reproducible Research and Data Analysis
- Open Research Data

- Open Research Software and Open Source
- Open Access to Research Papers
- Open Evaluation
- Public Engagement with Science
- Open Educational Resources
- Open Advocacy

Why should RI be taught?

It would seem obvious that the fundamental objective of teaching RI and RCR is to prevent research misconduct. This was certainly the original justification for the policies that NIH and later NSF have promoted to make RCR instruction mandatory for young researchers they funded^{1,4}.

The ubiquity of the belief that some sort of training is the main form of intervention to prevent RM and promote RI is well evidenced by results of the systematic review conducted by Ana Marusic and colleagues, who sought to find studies on interventions to prevent misconduct and promote integrity and found that "most interventions involved some kind of training"⁶.

However, it is by no means obvious that preventing research misconduct is a realistic goal of RCR instruction. Multiple analyses of data by the US office of research integrity, for example, have suggested that most cases of RM are generated by a complex combination of situational factors (e.g. moments of particular stress) and psychological traits⁷. Narcissism and psychopathy, in particular, are often predisposing factors in the most egregious cases⁸. Therefore, barring the cases in which RM is committed due to genuine ignorance of rules and methodologies, a course on RI is unlikely to have a direct effect on RM per se⁹.

This fact has been recognized for a long time. The first of ten recommendations made by Kalichman to "rescue" RCR education¹⁰ is to move away from expecting RCR to reduce RM, and clarify instead that "the primary goal of RCR education is to foster a research culture in which conversations about responsible conduct of research are expected and acceptable."

In addition to the general objective of fostering a culture of RI, there are three direct and realistic objectives that RCR instruction can pursue, the effects of which are likely to be positive both for researchers and for the quality of their work. Following a terminology used in relevant educational literature, these objectives aim to improve "knowledge", "skills", and "affective" components¹¹.

1) Knowledge: Knowledge about rules and policies relevant to research, as well as standards and practices that are conventional in specific fields or institutions, is conveyed by "instructional" contents. Students of such courses benefit from learning with clarity and in advance what must be done, what can and cannot be done, and are therefore equipped to avoid pitfalls. Institutions who impart such instruction are less likely to be held accountable for future infractions of rules on behalf of their members.

2) Skills: this is knowledge about "how to do", and is conveyed via forms of "process-oriented" instruction, which is aimed at teaching students how to navigate through complex issues pertaining to ethics, research integrity or even research methodology. Recipients of such training learn to recognize ethically challenging problems, can appreciate their complexity and can think through them to identify optimal solutions with greater sophistication.

3) Affective: The third objective, is less commonly appreciated, relates to affective components including "interests, attitudes, appreciations, values, and emotional sets or biases". In the context of RCR, improvements in the affective domain would translate, for example, in an increased interest in ethics and research integrity in general and a deeper appreciation for the importance and the complexity of ethical decisions in research.

More elaborate classifications, allowing more sophisticated and fine-grained course designs and assessments could also be considered. In their systematic review of interventions to prevent misconduct, for example, Ana Marusic and colleagues followed the scheme proposed by Kirkpatrick¹² and modified by Barr et al¹³, which includes multiple levels of

outcomes, hierarchically organized:

- Level 1 outcomes refer to learners' reaction to the intervention, including participants' views of their learning experience and satisfaction with the programme.
- Level 2a outcomes refer to modification of attitudes and/or perceptions regarding responsible conduct of research.
- Level 2b outcomes refer to acquisition of knowledge and/or skills related to responsible conduct of research.
- Level 3 outcomes refer to behavioural change transferred from the learning environment to the workplace prompted by modifications in attitudes or perceptions, or the application of newly acquired knowledge/skills in practice. This level was further divided into: 3a - behavioural intentions; and 3b - actual change in research or publication practices, or both.
- Level 4 outcomes refer to organizational changes attributable to the intervention.

3.1.2 Mode of delivery

How can RCR be taught most effectively and efficiently? Much of the scholarly research and debate around this question verges on three main options:

1) Traditional or "face-to-face" instruction

This is provided in person, via lectures, examination of case studies, peer discussions and possibly more interactive and engaging activities, such as role play.

Advantages of this approach include the greater depth of communication, interactivity and spontaneity that personal interactions allow. When taking part in a class or workshop, students have the opportunity to ask questions, share opinions, discuss with peers, and can also be stimulated more directly to engage with complex material that requires reflection and analysis¹⁴. Real cases of scientific misconduct could constitute a source of emotionally compelling and adequately realistic material to be examined, analyzed, and discussed in order to improve researchers' ethical decision-making skills.

The disadvantages of the traditional approach are primarily logistic. Face-to-face courses require all students and instructors to be present for one or a few days, and require a relatively large effort in planning and organization. From the point of view of content, face-to-face courses risk being too flexible and not sufficiently standardized to ensure that core instructional material is conveyed. Furthermore, the effectiveness of face-to-face courses is strongly dependent on the knowledge and skill of the instructor, whose teaching style may, moreover, not be equally suited to all students¹⁴.

2) Online instruction

Online training modules have been long proposed as an alternative to traditional RCR instruction modalities. Developed in some cases with research grants and freely available online, but in other cases developed and sold by commercial companies, such courses are typically structured in several modules that contain selected readings, images, videos and quizzes to assess the student's comprehension.

Online delivery arguably obviates to some of the drawbacks of face-to-face instruction. In addition to providing a standardized learning environment, online courses permit the collection of instant feedback from students, can be rapidly updated and improved whenever necessary, and can be scaled to large audiences. These advantages, however, are only allowed by online courses developed and delivered by the teaching institution. It is less clear if and how commercially available courses can be adapted to student feedback. Moreover, if commercial courses charge a per-student fee, then scaling the course to large audiences entails a corresponding increase in costs, with no saving on resources.

Furthermore it is suggested that online learning increases the ability to learn complex material, because it allows a non-linear interaction with the course contents. This educational advantage, however, remains contentious¹⁴. It is even less clear if and to what extent online learning is able to impart greater cognitive skills, such as the ability to generate ideas, reflect, negotiate and manage complex situations, all skills that are relevant to RCR instruction.

3) Hybrid formats

A hybrid format, often called "blended learning", is the natural third alternative to the two above.

In principle, a hybrid format could allow to reap the benefits of both face-to-face and online learning and avoid their respective drawbacks. However, hybrid formats have their limitations, too. For example, in a hybrid course, students only intermittently interact with their instructors, which may hinder some of the advantages of the traditional approach. Furthermore, novice learners may suffer from the lack of personal instruction and guidance when engaging with the online material. Finally, developing hybrid courses requires considerable resources, which are likely to be larger than those for traditional instruction or online learning alone.

3.1.3 Assessment

In addition to the practical purpose of assessing if and how a particular course and instructor are effective, collecting data on a course effectiveness contributes to a great scholarly effort to improve RCR instruction. Beyond academic interests, assessing the effectiveness of RCR instruction with maximal rigour, objectivity and transparency is an ethical obligation of RCR instructors and of institutions that promote such instruction. As pointed out by Mumford et al. "Educational interventions, including RCR education, are costly for both the institutions offering the instruction and participants, with respect to their time. Thus, it is difficult to justify RCR education fiscally without adequate evaluation data. Thus, both substantive and fiscal concerns demand systematic evaluation of RCR programs."(pp39)¹⁵

In line with the format adopted in ordinary academic courses, RCR instruction assessment would ideally include both formative and summative assessment. The former would collect information on trainee reactions, in order to help the program operate smoothly. The latter aim to provide information about if and how trainees have changed as a result of taking the ethics training¹⁶.

How such assessment can be most effectively and rigorously conducted is a matter of considerable research. It is well understood that, to some extent, the type of assessment needs to be tailored to the objectives of the course. For example, if the objective is to impart knowledge, then questions testing the knowledge of students are most indicated. If instead the objective is to impart skills, such as more sophisticated thinking and procedural skills, then students should be assessed with regards to how they analyze and respond to specific scenarios.

To summarize, RCR training can vary across multiple dimensions. Courses may differ in their objectives and intended audience, which entails that different modes of delivery and different modes of assessment may be required. This already considerable diversity of options and possibilities is enormously multiplied once it interacts with the diversity of disciplines and national, cultural, institutional contexts in which a course may operate. An overall challenge of RCR instruction, therefore, is to determine the optimal balance between generality and specificity of contents, relative to a given instructional objective and a given field, and accompany such choices with the right assessment procedure.

3.2 International documents and policies

European documents and reports send an unequivocal mandate to teach RI.

The European Code of Conduct for Research Integrity¹⁷, for example, states upfront that "Research institutions and organisations promote awareness and ensure a prevailing culture of research integrity" (page 5). In the section dedicated to Training, Supervision and Mentoring, moreover, the ALLEA document mandates that: "Research institutions and organisations ensure that researchers receive rigorous training in research design, methodology and analysis; Research institutions and organisations develop appropriate and adequate training in ethics and research integrity and ensure that all concerned are made aware of the relevant codes and regulations; "Researchers across the entire career path, from junior to the most senior level, undertake training in ethics and research integrity; Senior researchers, research leaders and supervisors mentor their team members and offer specific guidance and training to properly develop, design and structure

their research activity and to foster a culture of research integrity" (page 5). Further down, the ALLEA code of conduct reinforces the message by pointing out how "In their most serious forms, unacceptable practices are sanctionable, but at the very least every effort must be made to prevent, discourage and stop them through training, supervision and mentoring and through the development of a positive and supportive research environment " (page 9).

A similarly strong and clear view is expressed by Science Europe. Science Europe's Roadmap¹⁸, for example, specifies that "Promoting research integrity: this includes working with all relevant parties to articulate and promote the centrality of research integrity, most notably in the education and training of researchers" (page 22). In Science Europe's survey report on research integrity practices⁵, the importance of training for researchers and non-researchers is further stressed. The document reports how "Training interventions are vital in imbuing a culture of responsible conduct among researchers at all stages of the career pathway. Despite its importance, provision of research integrity training at national and local level is highly fragmented in most countries. The evidence base for what makes a successful training programme and how this should be delivered to different groups and levels of researcher is only now starting to emerge, but has not been collated in any systematic way that would allow informed choices on best practice." (page 26). Furthermore, the report states that "training in good research practices should not be confined to undergraduate students, but should be integral to the professional development of researchers/ research managers throughout their career: from senior researcher to undergraduate, from nurse to senior administrator [...] in addition, specific training would support members of ethics/integrity committees and ombudspersons in the demanding work that they do" (page 26).

The Bonn-Princeton statement, aimed at offering guidance for research organizations¹⁹ mentions the importance of training, in this case focusing more on RCR for researchers. Section 2 of the statement declares that "Providing Education, Training and Mentoring Institutions are responsible for offering training and education to increase integrity and prevent misconduct, based on state-of-the-art knowledge. This should focus on good research and research management practices, and the risks of misconduct. They should be oriented towards situations researchers might realistically encounter at their different career levels and research contexts. Discipline-specific resources should be used when available and relevant. Training should be tailored to the institution, and provide the researcher with insight into the routines and tools that are available when one finds oneself in a difficult situation. Inadequate mentoring and education of early career researchers is a risk factor for misconduct and supervisors bear a particular responsibility for the follow-up of early career researchers. However, education and training should be conducted at all levels, not only the Ph.D. level" (page 1026)

The importance given to RCR training by European Research Area policies could not be better illustrated by the calls, issued by the EC, to develop such training. For example, the 2017 call for Innovative methods for teaching ethics and research integrity²⁰, which, together with other less specific calls, has supported numerous projects that have developed numerous educational tools. Some of these projects are briefly presented below.

3.3 Ongoing European projects

ENERI

The "European Network of Research Ethics and Research Integrity" (ENERI) included a specific work package (WP4) with the aims to establish long-term effects for training initiatives for Research Ethics Councilors (RECs) and Research Integrity Officers (RIOs).

As they report on the project's website (<http://eneri.eu>), the main objectives of WP4 are "to prepare a core curriculum and advanced training modules on research ethics and integrity, which are also applicable for other stakeholders. Furthermore, to compile existing training materials including database on relevant case studies on research ethics and integrity and to provide training for countries where infrastructural lacks in research ethics

and integrity can be identified. [...] The ENERI partners developed a compendium of existing research ethics and integrity materials openly available and potentially suitable for training purposes of RECs and RIOs. " Examples of online training options are listed on the ENERI site at: <http://eneri.eu/online-available-training-options-for-recs-and-rios/>

PRINTEGER

The PRINTEGER (Promoting Integrity as an Integral Dimension of Excellence in Research) project also had work packages dedicated to the promotion and teaching of RCR. In particular, their work package D5.2 aimed to develop "Tools for research leaders and managers: addressing and stimulating integrity in research organisations" and its results are reported in: <http://printeger.eu/documents-results/> with results like Upright – a tool for teaching research integrity <https://printeger.eu/upright/>

VIRT²UE

The project VIRT²UE - Virtue based ethics and Integrity of Research aims to develop a "train the trainer program for upholding the principles of the European code of conduct". Its specific objectives include: to identify and consult ethics and research integrity trainers and the wider scientific community to understand existing capacity and deficiencies; to develop an innovative train-the-trainer programme; to create and update training materials for trainers and researchers; to implement, disseminate the train the trainer programme across Europe, ensuring the training of a significant number of trainers for each country (see <https://www.helsinki.fi/en/researchgroups/diversity-multilingualism-and-social-justice-in-education/projects/>)

Path2Integrity

The Path2Integrity project aims to support formal and informal learning methods by pursuing several objectives, including: establish excellent learning paths with research integrity role models and rotatory role-playing; develop and disseminate a Path2Integrity handbook of instruction for such tools; raise awareness of scientific facts about research integrity and role models in educational organisations; achieve widespread implementation of excellent learning paths; combine learning with with robust assessment methods; create units for learning research integrity that address everyone either directly or indirectly involved in research, including secondary school students, undergraduates, graduates, and young researchers (<https://www.path2integrity.eu/>).

Open science MOOC

As discussed above, the Open Science Massive Open Online Course aims to contribute to transform the scientific publication system by instructing researchers and other stakeholders on the principles and practices of Open Science, in its multiple components (<https://opensciencemooc.eu/>)

3.4 Platforms to collect RI resources

In addition to projects aimed at developing educational material, several initiatives are available or in development to provide infrastructure to support the exchange of information and educational material.

The EnTIRE consortium is a EU-funded network of ten partners that aims to create a dynamic online Wiki-platform, owned by the research ethics and research integrity (RE+RI)

community, that will make the normative framework governing RE+RI accessible (<http://www.entireconsortium.eu/vision/>).

EthicsWeb will be a common, decentralized European access point for information that is made available in different European member states, by various regional providers and centres as well as by international organizations. It aims to include information on ethics and science including training materials and training programmes (<http://www.ethicsweb.eu/node/213>).

The Research Ethics Library of the Norwegian National Research Ethics Committees is an active online resource aimed at offering introductions to the main issues in research ethics and to encourage debate and reflection. In addition to articles written by experts, it collects case studies, lists of suggested readings, links to other resources, relevant news articles and references. These resources cover several RI topics, including: research misconduct, whistle-blowing, authorship, conflicts of interest, bias, research methods, supervision, relevant national and international legislation and guidelines (www.etikkom.no/en/library/).

The European Network of Research Integrity Officers, finally, has an active website that also collects information on its member organizations, and resources on legislation and for training (<http://www.enrio.eu/resources/?cat=4>).

3.5 RI training by Participant Countries

Numerous training activities are already implemented on in preparation by organizations participating to the MLE. As Table 1 (on page 20) illustrates, these vary considerably in their objectives, intended recipients, compulsory or optional nature, and in their delivery and assessment methods.

4 LESSONS

4.1 Overview of recent studies

This section will first offer a brief overview of recent systematic reviews and meta-analyses that have examined the literature, often addressing multiple of the topics object of the MLE. It will subsequently draw a few general conclusions and recommendations that this literature consistently suggests.

4.1.1 Course scope and objectives

Ana Marusic and colleagues had the broad ambition to identify studies on multiple interventions to prevent misconduct and promote integrity in research and publication⁶. Their overall conclusion was that the quality of evidence overall was too poor and heterogeneous to permit a rigorous meta-analysis. Nonetheless, their non-quantitative conclusions were mostly in line with those of the meta-analyses discussed below, in suggesting that methods and content of training varied widely and were most effective when they involved interactive and practical activities. They also report a lack of studies that assessed outcomes at the institutional level.

Whereas studies that examine interventions are few and heterogeneous, reports on the conduction of courses in RCR and ethics more generally represent a considerable literature. A review by Mulhearn and colleagues²¹, for example, analyzed the content of 330 ethics training programs. Having noticed the wide diversity of characteristics of these programs, they employed a cluster analysis method to identify core types. Based on variables measuring instructional content, processes, delivery methods and activities, they identified 8 categories of instructional approaches: 1) Field-specific compliance; 2) Online; 3) Professional decision processes; 4) General discussion; 5) Targeted experimental interventions; 6) Norm adherence; 7) Exemplar based; 8) Philosophical self-reflection. They subsequently made comparison concerning the apparent effectiveness of these different types, and noticed a considerable variability within each cluster, showing that no

single type is univocally effective or not. Overall, they note how the number and diversity of objectives and instructional approaches in ethics education has increased in recent years.

Mulhearn et al's classification is just one of many possible. Kalichman and Plemmons interviewed RCR instructors regarding instructional goals of their programs. Combined, these trainers mentioned over 50 distinct goals²².

4.1.2 Course effectiveness

The effectiveness of such programs was analyzed in detail in a meta-analysis by Watts and colleagues, who examined 106 ethics courses and 150 effect sizes²³. In line with the assessments made by other authors, they notice the limitations inherent in the available data. These are characterized by a large variability in the measures and methods of assessment used, which, apart from reducing the accuracy of meta-analyses, also reduce their precision, because only a few effect sizes are typically available to assess any given combination of course objective and criterion. Moreover, they report strong evidence a file drawer problem: published studies reported effect sizes that were over twice as large, on average, than unpublished studies that could be retrieved (Cohen's $d=0.59$ vs $d=0.25$, respectively). Bearing in mind these limitations, the authors draw several general conclusions:

1) The quality and effectiveness of ethics training programs in the science appears to be improving. The average effect size measured in recent studies is considerably higher than that measured in a previous meta-analysis (i.e. Antes et al 2009²⁴).

2) These benefits appear to hold over time, with a few studies indicating positive effects two years after the course. Indeed, virtually no decay was suggested by the studies included in the review.

3) Employing multiple instructors with varying types of expertise is a critical element of success. However, little information is typically provided about how instructors are selected and trained.

4) Content developed "in house" (i.e. specifically targeted to a particular objective, field, class of subject and even institution) is more effective than "off the shelf" content.

5) Courses containing a mixture of specific and general objectives and material were less effective than courses that were field specific or field-general. Field-specific courses include, for example, courses that focused on professional guidelines as they apply within a particular field — such as authorship and publication practices, research design, data management, data integrity, intellectual property. Field-general courses may include instruction on general rules and regulations, institutional compliance, and field differences.

6) Courses that incorporate a variety of focused activities that encourage active participation are especially effective. "For example, activities that encouraged active processing of training content, such as class debates, note taking, and individual workbooks, all showed moderate to large gains. On the other hand, activities focused on social interaction, such as mentoring, service learning, and games, proved of less value. Finally, courses that emphasized instruction vis-à-vis cases, particularly longer cases of moderate complexity and low to moderate realism and emotional content, also showed sizable benefits to participants." pp380

7) Courses that focus on trainees within a particular field, using custom-developed (i.e. in-house) criteria, appear to be more effective than programs catered to trainees from multiple fields ($d = .20$ versus $d = .45-.66$).

The results of Watts et al's meta-analysis were largely confirmed by an alternative analysis of the same data, also conducted by Watts, that employed structural equation modelling, aimed to provide a general model for developing and improving RCR

education²⁵. In addition to reaching the same conclusions listed above, this analysis suggests that the most effective courses appear to benefit from coverage of guidelines and codes of conduct such as FFP, authorship practices, and intellectual property, among others. In addition, coverage of instructional content bearing on ethical decision making, such as virtues or character, professionalism, personal biases, and strategies, also appears to support RCR course effectiveness. Further, instructional content that encourages application of decision-making processes, such as analyzing emotions, motives, stakeholders, and constraints, also appears to be of value." ad that "Longer cases that evidence low to moderate complexity, affectivity, and realism appear to support instructional effectiveness." (page 647)

The relative effectiveness of online vs traditional methods of teaching RCR was examined in a meta-analysis by Todd et al¹⁴. Analyzing data from 106 ethics courses (the same data set used in other meta-analyses), they compared Cohen's d values of pre-post test effectiveness, relative to a course objective and content. Their overall conclusion is that face-to-face courses are most effective at delivering process-based contents. Online courses showed small effects in process-based content, but had effects comparable to face-to-face courses in conveying instructional content. Hybrid courses showed the greatest potential effectiveness, particularly if instructional, rule-based, compliance-related content is delivered online, and complex, process-based, analytical contents are delivered face-to-face. It should be noted, however, that face-to-face courses are also effective at delivering instructional material. Moreover, neither this study nor any of the other meta-analysis has compared the effectiveness of online and hybrid courses to that of traditional courses based on reading material and face-to-face lectures and activities.

Overall, therefore, meta-analytical evidence points to the importance of in-person activities to teach people how to examine and solve complex ethical issues, but does not prove that online instruction is a necessary complement to such activities, nor that it is superior to the simple provision of reading material to be discussed in person. A similar conclusion was reached in the Research Integrity Survey report by Science Europe⁵: " a paucity of empirical evidence about the most effective methods of training in research integrity, the experience of MOs that provide training is that active participation of students and researchers, rather than exclusive use of online resources, is most effective in facilitating discussion and learning. Active participation and blended learning includes case studies and role-playing. It is also important to ensure that trainers are appropriately trained, to introduce both knowledge and consistency into research integrity curricula" (page 27).

4.1.3 Course assessment

As discussed above, these conclusions need to be taken with caution, because the quality of available evidence is low. Part of the problem are unequal and generally low standards for evaluating ethics problems themselves. Procedures currently used for evaluating ethics education programs were examined by Michael Mumford and colleagues¹⁵ whose main conclusion was that evaluation ought to occur at at least two levels: within-program and across-program.

Within-program evaluation requires the use of multiple measures to assess the multiple objectives that a typical course has. Evaluation measures include, in decreasing order of popularity and relevance:

- 1) Behaviour, in which the performance of concern is measured. Due to the technical difficulties and costs in obtaining data on actual behaviour, this dimension is typically measured in "low-fidelity ethical decision-making measures" where the person is asked to read a scenario and respond to questions about it.
- 2) Cognition, in which the knowledge acquired is measured. Numerous measures of declarative, content-based knowledge have been developed and are routinely applied to assess RCR students.
- 3) Reactions, in which students are asked to rate various attributes of the course itself, such as the instructor's effectiveness, the clarity of the material etc.

4) Institutional outcomes, in which the effects of the course are assessed with regards to beneficial changes within the institution. Presumably, institutions aim to reduce the rate of questionable and unethical practices amongst their members, behavioural outcomes that are difficult to measure reliably. Research in this area, therefore, has instead relied on measures of ethical climate, which consist in surveys that are designed to assess how conducive the work is to ethical practices (see for example²⁶).

Cross-program evaluation, allows to assess which approaches are most effective. To make this level of evaluation possible and reliable, the effectiveness of programs should be systematically evaluated and the results should be published and shared.

Ideally, the effectiveness of a course should be evaluated in a pre-test/post-test comparison, with controls. Secondly, pre-post test, and if possible never just post-test assessment. More elaborate designs, however, could be implemented. For example one in which groups of students receive different versions of a course and then compared.

4.1.4 *Field generality vs. specificity*

Most data and experience in teaching RCR comes from the biomedical field, and in other disciplines, RCR training has been taken up more recently, if at all. The point is made most clearly, for the case in the United States, by an assessment of the impact of recent policies to promote RCR education by the National Science Foundation¹, which found that only 1% of university had content and requirements that differed by discipline.

Despite limitations of evidence outside biomedical research, a recent review was able to compare the effectiveness of RCR training in engineering, biomedical science, social science and "mixed fields"²⁷. Drawing evidence from 62 empirical studies, they identified two "golden rules" for RCR instruction that seem to apply across fields:

- **Golden rule n. 1:** Select either a field-specific or field-general content approach. Prior to developing a new ethics training course, instructors should consider whether their program should focus on field-specific or field-general content. Attempting to balance field-specificity and generality may contribute to an unfocused, loose discussion of ethics.
- **Golden rule n. 2:** Include processes in instruction. Ethics training programs are generally more effective when processes are included as part of the instruction. Processes can help trainees better understand how to approach ethical issues by giving them practice thinking through complex ethical scenarios.

In addition to the two golden rules, the authors suggested field-specific particulars that may be critical to RCR instruction success. As they report: "Engineers appear to benefit from instruction on effective collaboration as well as personal heuristics for solving ethical issues. Instruction in the biomedical sciences is generally more effective when major ethical issues and professionalism are key themes in training. Social scientists receive greater benefit from instruction on compliance and consideration of broader ethical issues applying to the field" (page 221)

Data for instruction of aspects other than RI and for non-researchers is even scarcer than that for RCR instructions outside biomedical research. A systematic review of training programs in editorial and peer-review practices³, for example, reported how, despite long-standing call for training in these roles and skills, evidence on the effectiveness of this training is scarce and of low quality "Included studies were generally small and inconclusive regarding the effects of training of authors, peer reviewers, and editors on educational outcomes related to improving the quality of health research. Studies were also of questionable validity and susceptible to misinterpretation because of their risk of bias. "

4.2 **Summary of current evidence**

What lessons can we draw from this evidence? With regards to the focus topics of the MLE, the following general conclusions can be drawn from recent studies:

Objectives:

- 1) The diversity of types and objectives of courses offered has increased, but there is much space for further development. At present, most experiences come from instruction on Ethics and RI aimed at research trainees.
- 2) Three fundamental types of objectives can be pursued: Instructional (imparting knowledge); Procedural (imparting skills); Affective (imparting interest, appreciation and awareness).
- 3) The objectives of a course need to be very clearly defined, because they determine how a course should be designed, conducted and assessed.

Mode of delivery:

- 1) Online training may only be effective if the objective is Instructional.
- 2) Courses that intend to impart skills and interest need to include in-person activities.
- 3) Different activities are best suited for different objectives, and courses are likely to be most effective if they combine several activities.

Assessment:

- 1) Assessing how a course has impacted its students is an essential component of RCR instruction.
- 2) Assessment should be conducted within a course, if appropriate with formative and summative assessment, as well as across courses.
- 3) The tools and scales to assess an RCR course need to be specific to the objectives of the course, and can assess multiple aspects of the reactions, knowledge, skills and behavioural changes of individuals, groups and institutions.
- 4) Course assessment is most accurate if measured with tools developed/adapted to the specificities of the course.
- 5) Assessment should be conducted before and after the course and, ideally, with a control group.

Cross-disciplinarity, generality and specificity:

- 1) Disciplines have clear specificities that courses need to be tailored to. A similar argument is likely to apply to country and even institution specificities.
- 2) Courses should either be expressly designed to be cross-disciplinary in their content and objectives, or should be specific to a discipline. Hybrid courses are unlikely to meet their objectives.

Sharing data:

- 1) Data currently available on RCR instruction is very limited. Most studies are conducted in the United States and are not independent, as they are based on overlapping data sets, which are often analyzed by overlapping team of authors.
- 2) Current systematic reviews document that available data is of poor quality and possibly subject to significant research and reporting biases.

- 3) Examining real or realistic cases in which questions of research integrity are raised is an effective tool in imparting procedural knowledge as well as in assessing the acquisition of critical thinking skills.

5 CHALLENGES

In light of the literature reviewed above and of the information gathered about participating countries, some of the MLE objectives can be focused on more specific targets. In particular, the literature consistently suggests that RI education should ideally strive to be: face-to-face or hybrid, especially if the objectives are not merely instructional; developed in-house by the teaching institution; tailored to a discipline and/or topic; based on variety of activities, as suited to different objectives; assessed by adequate methodologies and measures. Moreover, several projects are developing tools training material and platforms to share RI relevant information.

Therefore, MLE participants could share experiences and opinions most profitably on the following priority topics:

- 1) Which course objectives have been, will be, or should be prioritized in a given country/institution/target audience: knowledge, skills or affective?**
- 2) What approaches, materials and incentives were implemented to pursue such objectives, and with what results?**
- 3) What modes of assessment were implemented, if any, and what were the advantages and disadvantages?**

Furthermore, two overarching challenges and long-term policy objectives that could start to be addressed at the MLE are:

- 4) How should RI instruction be most effectively coordinated within countries and across the EU, given the diversity of national and institutional cultures and priorities?**
 - a. What specific elements of RI instruction should remain (or be made more) uniform:
 - i. At the national level?
 - ii. Across the EU?
 - b. Which specific elements of RI instruction should remain (or be made more) diverse?
 - i. Across the EU?
 - ii. Within each country (at the institutional level)?

Elements to consider could be any aspect of the design of a course: Objectives, Topics, Forms of incentives, Methods of assessment.

- 5) How can information and data about RI instruction be most effectively shared across Europe?**
 - a. What components of course materials would it be most useful to share?
 - b. What course materials can be shared? And in what form?
 - c. Could existing organizations and/or platforms facilitate the exchange of know-how and/or the sharing of data online? If so, how?

The kinds of information to discuss include: case studies of real cases of misconduct, course syllabi, course materials, tools for course assessment, data on course assessments, general experiences in running RI instruction.

Table 1 Education programs for RI in participant countries, with key characteristics. The list is intended to be illustrative and not exhaustive. For example, it excludes the innumerable academic courses and degrees in ethics, bioethics, sociology and philosophy of science that university students can take, but it includes ethics courses that are compulsory for students of all disciplines.

Country	National or inter-university RI body	Training offered and topics/objectives	Compulsory or optional?	Are outcomes assessed?	Mode of delivery	Source
Austria	Austrian Agency for Research Integrity	RCR and train the trainer programs, with topics including: -Agency for Research Integrity -Good Scientific Practice -Data Management -Citation and Plagiarism -Publication and Authorship Responsibility of supervisors, early stage researchers and institutions	Usually voluntary; compulsory for doctoral programs funded by the national funding agency (FWF) and, in some universities, for all PhD students and/or medical students.	Universities usually have a feedback form for (all, therefore very general) lectures, workshops and seminars: post-course In some courses there is also a final exam on RI issues and ethical thinking.	Lectures, workshops. By now only face-to-face; online (not commercial) is planned as an addition for a blended learning approach. Usually have half- of full day workshops; the train the trainer is two days long. Modes: lectures, discussions, case studies, group work, role plays, films,...trying to be as interactive as possible	oeawi.at
Bulgaria	Committee on Academic Ethics	Organisation of special integrated training courses (in progress) about publication and peer review, and framed in the context of researchers' goals.	Optional		practical courses	
Denmark	Danish Agency for Science and Higher Education					ufm.dk
Estonia	Estonian Research Council (ETAg)	ETAg has organized several workshops and seminars for the whole community during the past years.	Optional		workshops and seminars	etage.ee

Finland	Finnish National Board on Research Integrity (TENK)	TENK offers training for research integrity officers of universities, universities of applied sciences, and publicly funded research institutions. TENK has created a network of Research Integrity Advisers. Since the start of 2017, TENK has trained more than 100 advisers in more than 60 research organisations to provide low threshold, personal advice on research integrity.				tenk.fi
France	French Office for Research Integrity (OFIS)	Universities organise training in research integrity and research ethics. Doctoral schools offer courses for all PhD students before defending their thesis. Training aims at: -Informing PhD students about research integrity issues -Alerting them to the mechanisms that can lead to scientific misconduct -Encourage them to develop a sense of responsibility and conduct themselves in a spirit of scientific integrity.	Compulsory: by 2016 ministerial decree, PhD programmes have to include mandatory training on ethics and research integrity	Doctoral schools must ensure that doctoral students benefit from training in ethics and research integrity. Integrity officers, appointed in each public institution, monitor training programs.	Mode of delivery depending of institutions: PhD courses in person; workshops (lectures, role play); seminars, online courses, etc. eg: - seminars, thematic working groups, and colloquia, organised by the Research Ethics and Scientific Integrity Council (POLÉTHIS) at Université Paris-Saclay: https://www.universite-paris-saclay.fr/en/polethis - MOOC on ethics, provided by university of Lyon: https://www.fun-mooc.fr/courses/course-v1:universite-lyon+91001+session01/about - MOOC on research integrity, provided by university of Bordeaux: https://www.fun-mooc.fr/courses/course-v1:Ubordeaux+28007EN+session01/about	National network of doctoral colleges : https://rncd.fr/contact/
	OFIS	is planning regular workshops with and for research integrity officers, in order to share their experience through illustrative cases studies, and to provide practical advices.	Optional			
	CIRAD, CNRS, INSERM, INRA, and other public research institutions.	training on RI for their employees				
	The National funding Agency (ANR)	Training in ethical principles, prevention and management of conflicts of interest for ANR employees and for members of scientific evaluation panels, to support them and ensure these rules are respected.	Optional			https://anr.fr/en/anrs-role-in-research/values-and-commit

						ments/scientific-integrity/
Greece	RCR-Greece (Network for Responsible Conduct of Research in Greece)	Recently started RCR programs, aimed at Master's students, in two Greek Universities in Research Integrity.	Optional		Lectures	http://www.rcr.gr/index.php/en
	National Technical University of Athens (NTUA)	Train the trainers program, part of the EU funded project VIRT2UE (see section 3.3), on RE & RI issues, for junior and senior researchers.	Optional	Pre-course and post-course assessment of knowledge on RI, assessment of the training after its completion.	Face-to-face multi-day training workshop, including various exercises (discussion-debate, group activities, dilemma game etc.) and on-line supporting material (<i>blended learning approach</i>).	http://www.semf.ntua.gr/en
		NTUA organizes seminars/short courses on Research Ethics and Research Integrity for post graduate students. The seminars are given by members of the NTUA's Research Ethics Advisory Committee	Optional		Seminars	
Ireland	National Forum for Research Integrity (NFRI);	Minimum-level of research integrity training for all higher education institutions and state-funded research institutions. This is a three year pilot, starting January 2018 which provides access for 15,000 users (>50% of those eligible). The three target groups for the training are 1) Academic staff 2) Research staff 3) Postgraduate research students (Masters by Research and Doctoral Candidates). Research institutions can distribute their access tokens across these three target groups based on their own strategy.	Compulsory for researchers funded by grants from Science Foundation Ireland, the Health Research Board, the Environmental Protection Agency and Horizon 2020. Institutions can decide whether training is optional or compulsory for each of the three target groups. Institutions can decide whether training is optional or compulsory for each of the three target groups. For example, the Technological University of Dublin has incorporated the online training into its	The National RI Forum will use the inbuilt "Impact Module" to assess the impact of the training at national level.	Online, commercially provided. Several institutions (e.g. University College Cork and National University of Ireland Galway) are using the online training in a blended format with in-person workshops.	

			Structured PhD programmes, with 5 ECTS awarded for attending a 2-hour RI workshop followed by completion of the online course.			
Lithuania	Office of the Ombudsperson for Academic Ethics and Procedures	Training to librarians (e.g. preventing plagiarism), researchers (e.g. conflict of interest/roles) and academic integrity committees (e.g. categorising academic malpractices)	Optional		Workshops.	http://www.etika.gov.lt/lt/
Luxembourg	Luxembourg Agency for Research Integrity (LARI)	The staff of LARI teach RE and RI at the major research institutes in Luxembourg. Good Scientific Practice workshops are offered by the Univ of Lux and LIH, with LARI staff as faculty. LARI also trains Coaches who provide support, encouragement, and guidance as researchers progress along their project path, to help researchers produce robust, ethical research.	Optional		Seminars. LARI uses the CAPRI (Creative Approaches Promoting Research Integrity) which consists of a novel blend of didactic and hands-on creative activities.	lari.lu
Moldova	All universities	Courses on "ethics and professional culture" and courses on "research methodology and professional ethics", at under-graduate, graduate and postgraduate level, designed by faculty members, for all disciplines. Modules include topics such as: Classification of scientific research methods; The economic dimension of quality in scientific research; Improving competitiveness and accountability in scientific research; Copyright Law; Good conduct in scientific research; Presentation of the results of scientific research; European regulations in the field of research, development and innovation; ERA bodies and services; National legislation dedicated to research, development and innovation.	Compulsory, by Ministry of Education decree. The list of obligatory and optional courses, and their structure are established by the institutions, according to the specifics of the general field of study/study program, in compliance with the National Qualifications Framework, as well as the institution's mission in staff training.	Standard academic examination.	Academic seminars and lectures	
		Lectures in open access and open science, e.g. Open Science in the Republic of Moldova and Open Science in the EU.	The promotion of the concept of Open Science was established by Government Decree	No	Seminars and presentations	https://mecc.gov.md/sites/default/files/plan_cadru_meserii_con

						exe_act_ualizat.pdf
Norway	National Research Ethics Committees (Etikkom)	<p>Several national initiatives related to training:</p> <ul style="list-style-type: none"> - A Research Ethics library containing articles and cases (including on RI). This is an online resource for research Ethics/RI education. -The Committees are working on "a curriculum on RI/RM" for members and staff connected to local Research Ethics. -The secretariat for the Committees are participating in different teaching activities, including presentations etc. at different institutions. - A yearly conference is organized for teachers and people responsible for RI at the different institutions. 	The Research Ethics Act of 2017 requires research institutions to provide training in research ethics			www.etikkom.no
Spain	Ethics Committee of the Spanish National Research Council - CSIC	<p>Several members of the CSIC Ethics Committee give lectures regarding research integrity and responsible conduct of research. Seven lectures were given last year 2016.</p> <p>Other institutions include seminars in the PhD training courses</p>	A 2015 National Statement of Scientific Integrity signed by the major research institutions recommends training of staff members in ethical matters and practices		Lectures and seminars	https://www.cruce.org/documentos/20compartidos/Informes%20y%20Posicionamiento/Declaracion%3%B3n%20Nacional%20Integridad%20Cient%3%ADficial_.pdf

Sweden	Group on Research Misconduct at Ethical Review Appeal Board	The Swedish research council (VR) is currently working on an Ethical policy to inform and promote good research practice among the grants applicants. The ethical policy covers <i>the research that is funded, the application process and the funding decision process</i>				
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