Planning Patient Engagement

Educational scenarios on competing interests and conflicts of interest

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Contents

Introduction

PARADIGM (Patients active in research and dialogues for an improved generation of medicines) was an IMI funded multi-stakeholder consortium to provide a framework for structured, effective, meaningful and ethical patient engagement along the lifecycle of medicines.

The project focused on three decision-making points: research priority setting; clinical trial design; and early dialogues with regulators and health technology assessment (HTA) bodies. The result of the consortium/the output of the consortium is a comprehensive set of tools and practices to support the integration of the patient perspectives into medicines development beyond the focal areas of the project.

Patient engagement should be a standard practice to improve medicines development and deliver results that are focused on patients' needs.

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What is this tool?

This tool describes educational scenarios that will help patients to make informed decisions when they decide to engage with one or more than one other type of stakeholder, and to raise awareness among the engaging stakeholders about the potential consequences of doing so. They explore hypothetical situations and possible actions for the management of competing interests and conflicts of interest during patient engagement in medicines development. This tool is based on the document **Raising awareness on managing competing interests in a multi-stakeholder environment: Guidance to patients and engaging stakeholders** (http://imi-paradigm.eu/PEtoolbox/conflict-of-interest).

For the purpose of this tool we define:

- **Competing interests** as those that may affect an individual's impartiality but that do not constitute a conflict per se. They should be declared for transparency purposes.
- **Conflict of interest** as a situation in which the individual's judgement may be perceived as being affected by a secondary interest, as defined by the engaging stakeholder(s).

Before using this tool please review relevant glossary that apply to the contents of this tool.

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Why is it important to understand competing interests and conflicts of interest (CoI) and how to manage these?

Medicines development is a complex and continuously evolving multi-stakeholder environment where the engagement of patients in the development process may occur at:

a. multiple times with the same stakeholder
b. across several different stakeholders simultaneously, and
c. through varying mechanisms and degrees of complexity of engagement.

Interactions between the patient community and the engaging stakeholder should be based on mutual transparency, respect, autonomy and independence. Raising awareness of the consequences the patient engagement activity might have is important for both patients and the engaging stakeholder organisation. Early identification of potential competing interests is key for their effective management. Measures could be put in place to avoid or limit the extent of the conflict and the subsequent impact to the patient's ability to engage in present and future interactions. Mitigation measures may vary according to the stakeholder type.

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Example of competing interests vs conflicts of interest

https://imi-paradigm.eu/PEtoolbox/COI-Annex-Competing-interests-vs-conflicts-of-interest.pdf

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Why and how to use educational scenarios

- The following scenarios are used to highlight some common scenarios faced by the relevant stakeholders when engaging with patients in medicines development.
- Identifying and managing potential competing interests and conflicts of interest is complex. These examples are not designed to be exhaustive or suggestive of every possible scenario. Additional resources are included at the end with further information to help manage competing interests and conflicts of interest.
- In each scenario, there are no fully right or wrong answers. **Select what is probably the most appropriate response**. This will demonstrate the impact that such response might have on the patient, any potential conflict it might raise, and the patient's potential ability to interact with other stakeholders in a similar manner. The preferred response will be highlighted in bold font. A rationale for all possible answers will be provided.
- The co-creation of these scenarions was inspired by the situational judgement test methodology, which is used to assess judgement or knowledge of appropriate behaviour in work-related settings (see Additional resources).

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Learning objectives

- Understanding the potential impact of multi-stakeholder interactions
- Identifying and managing competing interests and conflicts of interest
- Damage control and mitigation measures

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Scenarios

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1: You work for a medicines developer and would like to involve a patient to discuss patient-relevant endpoints for the design of a clinical trial. Would this influence the patient's ability to engage with other stakeholders?

A. No, not at all

B. Yes, it will prevent the engagement of this patient with any other stakeholder

C. Maybe. This depends on the policy for management of competing interests of the other stakeholder and the type of activity in which the patient will be involved

CLICK HERE TO RATIONALE

1: You work for a medicines developer and would like to involve a patient to discuss patient-relevant endpoints for the design of a clinical trial. Would this influence the patient's ability to engage with other stakeholders?

A. **No, not at all**

B. **Yes, it will prevent the engagement of this patient with any other stakeholder**

C. **Maybe. This depends on the policy for management of competing interests of the other stakeholder and the type of activity in which the patient will be involved**

Rationale

A. Patients are in a central position to engage with each and every stakeholder along the medicines development process and therefore their interests are under scrutiny by the engaging stakeholder. Patients often engage with multiple stakeholders simultaneously and over time. The early identification of potential competing interests is key to effectively manage them upfront in order to avoid or limit the extent of the conflict and the subsequent impact to the patient's ability for further interaction.

B. Raising awareness about the potential consequences of the engagement, both among medicines developers and the patient community, will help patients to make an informed choice when they engage with a stakeholder, and will help to mitigate the risks of potential conflicts of interest.

C. The type of interaction and the consequences derived from it, may be different depending on the groups involved. Thus, each stakeholder group defines the type of and rules for engagement with their stakeholders. The engaging stakeholder and process of engagement define what represents a conflict of interest.

2: You are a patient advocate and are keeping a record of your interactions with different stakeholders (in relation to medicines development). What type of interactions should you list in your log of activities?

A. Only the ones for which you have received compensation and/or remuneration

B. All of them

C. I don't keep a record of my activities, it is not useful

CLICK HERE TO RATIONALE

2: You are a patient advocate and are keeping a record of your interactions with different stakeholders (in relation to medicines development). What type of interactions should you list in your log of activities?

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B. All of them

C. I don't keep a record of my activities, it is not useful

Rationale

A. Only keeping record of the interactions for which you have received compensation/remuneration is not recommended. For some stakeholders (e.g. regulators) paid or unpaid consultancy (i.e. strategic advice) could lead to a conflict of interest.

B. Keeping track of all your engagement activities with various stakeholders, is very important to help you correctly declare your interests to the engaging stakeholder (e.g. regulators, HTA bodies, payers, medicines developers).

C. Not keeping any records may make it difficult to complete the declaration of interest form, as in most cases you would need to declare activities from past years. Failing to keep accurate records increases the possibility of a perceived conflict that may exclude you from some engagement activities.

3: You are a patient advocate and are aware of opportunities to be involved with one or several medicines developers who are developing therapies for your disease of interest and with regulators/HTA/payers. What do you do?

A. You refuse all of them because you don't know what to choose

B. You accept them all because these are all good opportunities to be impactful

C. You discuss with the other patient advocates in your field/organisation in order to distribute the roles amongst yourselves

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Rationale

A. Maximising the patient's expertise and commitment opportunity is vital, but not at the cost of a missed opportunity where no stakeholder benefits. Seeking advice from your patient organisation is recommended.

B. Likewise, poorly managed opportunities can quickly become overwhelming for patients and could result in temporary or long term exclusion from future interaction(s). Simultaneous engagement with several medicines developers might result in a conflict of interest. Transparency about any previous or current engagement with another stakeholder is required. The engaging stakeholder, according to their policy/rules, will ultimately decide if the engagement should take place.

C. Building firewalls between engagement and advocacy activities in patient organisations is one of the strategies to mitigate potential conflicts of interest. Patient organisations, through their patient engagement functions should inform individual patients about the consequences of their engagement with one stakeholder or another. The common knowledge generated in the disease community is shared, but the division of roles ensures that the confidentiality of discussions with the different stakeholders is maintained and CoIs can be avoided.

4: You work for a medicines developer and have involved a patient in the development of one of your products. Would it still be possible for this patient to be invited as a patient expert by the European Medicines Agency?

A. Yes, without any restriction

B. No, it won't be possible anymore

C. It depends

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Rationale

A. The interaction of a patient with a company may prevent them to subsequently/ simultaneously be involved in some activities at the EMA.

B. If the interaction of a patient with a developer was before the period requested for reporting, participation in certain activities may be accepted.

C. Normally, it is the interests that are current or within the last 3 years that are assessed. For certain activities, past interests beyond the 3-year threshold must be declared. In addition, on some occasions mitigation measures apply, such as the 'expert witness' status that allows patient's participation under specific conditions. See EMA policy on handling competing interests (https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-declarations-interests-scientific-committees_en.pdf)

5: You work for a medicines developer and have been invited to a discussion meeting with regulators in the context of a Scientific Advice procedure. The regulators have invited a patient who you know but have never been involved in any of the developer activities you represent. What do you do?

A. You act the same way as with the other people present in the room

B. You ignore them as it might be perceived as a conflict of interest if you say 'hi' to them

C. You call them after the meeting to debrief and ask their opinion on how the meeting went

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Rationale

A. In this case, the patient is an independent expert that has been invited by the regulators the same as any other expert. For full transparency disclosing that you know each other to the regulators is advisable. Do not invite the patient to support your responses to the regulators questions as this could be perceived as a conflict of interest.

B. If you know a patient attending the meeting, do not hesitate to acknowledge it and state that no exchange has occurred over this dossier. This will help to avoid wrong perception of the situation.

C. The patient has signed a confidentiality agreement and is not allowed to discuss the contents of the meeting. Doing so may be considered a breach of trust and may impact the related procedure.

6: You are a patient advocate and there are several product development programmes ongoing at the same time within different medicines developers that could benefit from patient insights. What should you do?

A. Interact with only one of them

B. Interact with several of them in parallel

C. Explore whether a Community Advisory Board could be set up

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6: You are a patient advocate and there are several product development programmes ongoing at the same time within different medicines developers that could benefit from patient insights. What should you do?

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B. **Interact with several of them in parallel**

C. **Explore whether a Community Advisory Board could be set up**

Rationale

A. Depending on the (limited) capacity of the patient organisation this may be their only option. However, subsequent or parallel engagement with regulators/HTA bodies/payers may be restricted.

B. Engaging with multiple medicines developers simultaneously requires a significant number of trained patient advocates. It also means that all patient organisation resources face potential conflicts of interest in a subsequent or parallel engagement with regulators/HTA bodies/payers. Diversification of human resources in order to be able to meet the different engagement requirements may be put in place to mitigate that risk.

C. Community Advisory Boards (CABs) allow for multiple engagement with several medicines developers. The community contacts the different organisations with whom they want to collaborate and decides who from the community will attend the meeting. However this is not the only option and does not fit all the situations, e.g. it might be not suitable in the case of a very rare disease, with a small number of (trained) patient advocates. At the moment, being a CAB member is considered consultancy by the EMA, and hence considered a direct interest and associated with the highest level of restriction.

7: You are a patient advocate and you receive a proposal to be involved in a Registry committee for an ultra-rare disease. This registry is led by academics/clinicians but sponsored by a medicines developer. If you accept, will you still be able to engage with the European Medicines Agency?

A. Yes, it is a registry, not a development programme

B. Yes, as expert witness (i.e. with some restrictions compared to patient expert status)

C. No, the registry is funded by a medicines developer

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A. **Yes, it is a registry, not a development programme**

B. **Yes, as expert witness (i.e. with some restrictions compared to patient expert status)**

C. **No, the registry is funded by a medicines developer**

Rationale

A. The primary goal of a registry may not be therapeutic development. However, it provides information for medicinal product development.

B. When diversification of the roles between several patient advocates is not feasible, such as in the case of an ultra-rare disease, patients might be involved with the EMA as an 'expert witness'. In this case, the expert witness will have a role limited to testify and give specialist advice on a specific issue by providing information and replying to any questions only. The expert witness may have restricted access to the relevant documents or may be asked to leave the discussion at some point.

C. Even if the registry is led by academics/clinicians, the funding comes from one single company. The involvement of a patient in the governance of such a registry may be perceived as a conflict of interest.

8: You are member of an EMA Committee representing patients. In which of the below activities can you be involved?

A. A public/private partnership consortium such as IMI PARADIGM

B. A closed meeting with several medicines developers

C. A workshop or a conference with several medicines developers

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8: You are member of an EMA Committee representing patients. In which of the below activities can you be involved?

A. A public/private partnership consortium such as IMI PARADIGM

B. A closed meeting with several medicines developers

C. A workshop or a conference with several medicines developers

Rationale

A. Public/private partnership consortia have defined rules of interaction and focus on broader intersecting issues/topics not related to any particular medicinal product or an individual medicines developer.

B. A closed meeting is defined as a meeting that is held behind closed doors, usually upon invitation only and organised by one or several companies, or by a trade association, for example. A closed meeting whether it is with one or several companies is considered as giving strategic advice/consultancy as per EMA policy.

C. In contrast, conferences or workshops with a public agenda or programme and open registration do not generally result in a conflict of interest.

9: You are a patient involved in a clinical trial. Will it still be possible for you to be invited as a patient expert by the European Medicines Agency?

A. Yes, without any restriction

B. No, it won't be possible anymore

C. It depends

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B. No, it won't be possible anymore

C. It depends

Rationale

A. Participation in clinical trials will not result in the Agency restricting patient involvement in its activities, unless a specific interest is identified. However, for transparency purposes, involvement in a trial and in publicly funded research/development initiatives, as well as membership of an ethics committee, should be declared on the declaration of interest form.

10: You are a patient who works in a government hospital and have been invited to participate in a patient advisory board (PAB) of a company to discuss the unmet needs of your condition. Do you think that your professional role can affect your participation?

A. No, my professional role will not influence my participation in the PAB

B. Yes, the company might consider that my role may give rise to a conflict of interest

C. It depends

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10: You are a patient who works in a government hospital and have been invited to participate in a patient advisory board (PAB) of a company to discuss the unmet needs of your condition. Do you think that your professional role can affect your participation?

A. **No, my professional role will not influence my participation in the PAB**

B. **Yes, the company might consider that my role may give rise to a conflict of interest**

C. **It depends**

Rationale

A. If you are working as a nurse in a government hospital, this might not be considered a conflict of interest.

B. If you are having responsibility within the purchasing department of a government hospital, this is much more likely to be considered a potential conflict of interest.

C. Medicines developers have their own policies to engage with patients and other experts that require declaration of interests that may have a perceived influence on the company's business. Employment in public organisations in a role that could influence decision-making over the company's business may restrict the involvement.

11: You are a patient advocate and have been invited to speak at a scientific conference open to the public to give a patient testimony of your disease. Will you still be able to engage with regulators/HTA bodies?

A. Yes

B. No, as my travel and accommodation expenses were covered and I have received a speakers fee by a medicines developer organising the session

C. Yes, as I did not receive any honorarium/speaker's fee for my contribution. However, my organisation usually receives funding from the medicines developer sponsoring the conference

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B. No, as my travel and accommodation expenses were covered and I have received a speakers fee by a medicines developer organising the session

C. Yes, as I did not receive any honorarium/speaker's fee for my contribution. However, my organisation usually receives funding from the medicines developer sponsoring the conference

Rationale

A. Participation in a scientific conference open to the public and without receiving any honorarium/speakers fee will not prevent you from engaging with regulators/HTA bodies.

B. Financial interests are under scrutiny by the engaging stakeholder and usually considered direct interests, and therefore patients might be excluded or their involvement severely restricted.

C. Participation in a scientific conference open to the public and without receiving any payment will not prevent you from engaging with regulators/HTA bodies. However, you should disclose any funding from a medicines developer received by your patient organisation. Regulatory and HTA bodies have different policies in regards to the amount of funding received by medicines developers and may apply different levels of restriction to the involvement.

12: You are a patient in a clinical trial for a medicine with Company A. Company B is working on a similar medicine and has invited you to provide advice to them. Company B does not know about the novel medicine Company A is working on. What should you do?

A. You give simultaneous advice to both companies without letting them know

B. You decide to engage with company B disclosing your participation in the clinical trial

C. You decide not to accept the engagement opportunity with company B as you want to avoid a potential conflict with company A

CLICK HERE TO RATIONALE

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B. **You decide to engage with company B disclosing your participation in the clinical trial**

C. **You decide not to accept the engagement opportunity with company B as you want to avoid a potential conflict with company A**

Rationale

A. Patient engagement is a trust based collaboration between patients and the engaging stakeholders. Before the engagement occurs you should be transparent about your previous and current engagement activities.

B. Transparency about any previous or current engagement with another stakeholder is required. However, you should be mindful not to disclose any confidential information when declaring your participation in the clinical trial. The engaging stakeholder, according to their policy/rules, will ultimately decide if the engagement occurs.

C. You may decide not to engage with company B to avoid a potential conflict with company A. Seeking advice from your patient organisation is recommended. Patient organisations, through their patient engagement functions should inform individual patients about the consequences of engagement with one stakeholder or another. They can also help identify a representative free from any potential conflict that could participate in the activity.

Key concepts

- Importance of raising awareness among all stakeholders of the potential consequences of patient engagement
- Transparency, disclosure, compliance with signed agreements as a key element before starting any patient engagement activity

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Additional resources

- **Raising awareness on managing competing interests in a multi-stakeholder environment: Guidance to patients and engaging stakeholders**
  http://imi-paradigm.eu/PEtoolbox/conflict-of-interest
- **PARADIGM Code of conduct on patient engagement**
  http://imi-paradigm.eu/PEtoolbox/code-of-conduct
- **European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts**
  https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-declarations-interests-scientific-committees_en.pdf
  Last accessed 10 May 2020
- **EUnetHTA Procedure Guidance for handling Declaration of Interest and Confidentiality Undertaking (DOICU) Form**
  https://www.eunethta.eu/wp-content/uploads/2019/04/EUnetHTA-DOICU-Procedure-Guidelines.pdf
  Last accessed 10 May 2020
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- Pangallo, A., Zibarras, L. and Patterson, F., 2016. **Measuring resilience in palliative care workers using the situational judgement test methodology.** Medical education, 50(11), pp.1131-1142.

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Glossary

http://imi-paradigm.eu/PEtoolbox/COI-Glossary.pdf

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