

Congresso SPO 2024

Focus Group:

Preparação da mesa redonda

“Investigação clínica da iniciativa do investigador em Portugal: desafios e oportunidades”

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Amsterdam UMC**

28 Out 2024





Ciência da Implementação

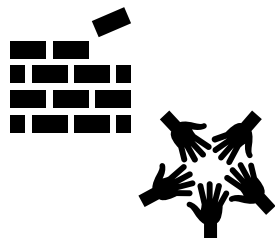


Source: <https://arc-si.nihr.ac.uk/research-and-implementation/our-research-areas/implementation-science>

“Implementation science is defined as the **scientific study of methods** to **promote** the **systematic uptake** of research **findings** and other EBPs into **routine practice** to improve the quality and effectiveness of health services and care” (1)

(1) Eccles MP, Mittman BS. Welcome to implementation science. Implement Sci. 2006;1:1.

Como pode a Ciência da Implementação ajudar?



IDENTIFY FACTORS
influencing
implementation



IDENTIFY STRATEGIES to
accelerate adoption of
practices, policies and programs



**DISSEMINATE AND
SCALE UP** effective
interventions

Objectivos do painel de discussão “*Investigação clínica da iniciativa do investigador em Portugal: desafios e oportunidades*”

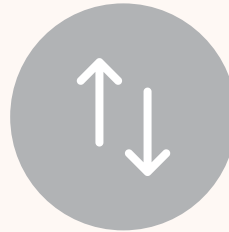
Objectivos da reunião de hoje

Preparação da mesa redonda

“Investigação clínica da iniciativa do investigador em Portugal: desafios e oportunidades”



1 – IDENTIFICAR OS
“DETERMINANTES” RELEVANTES



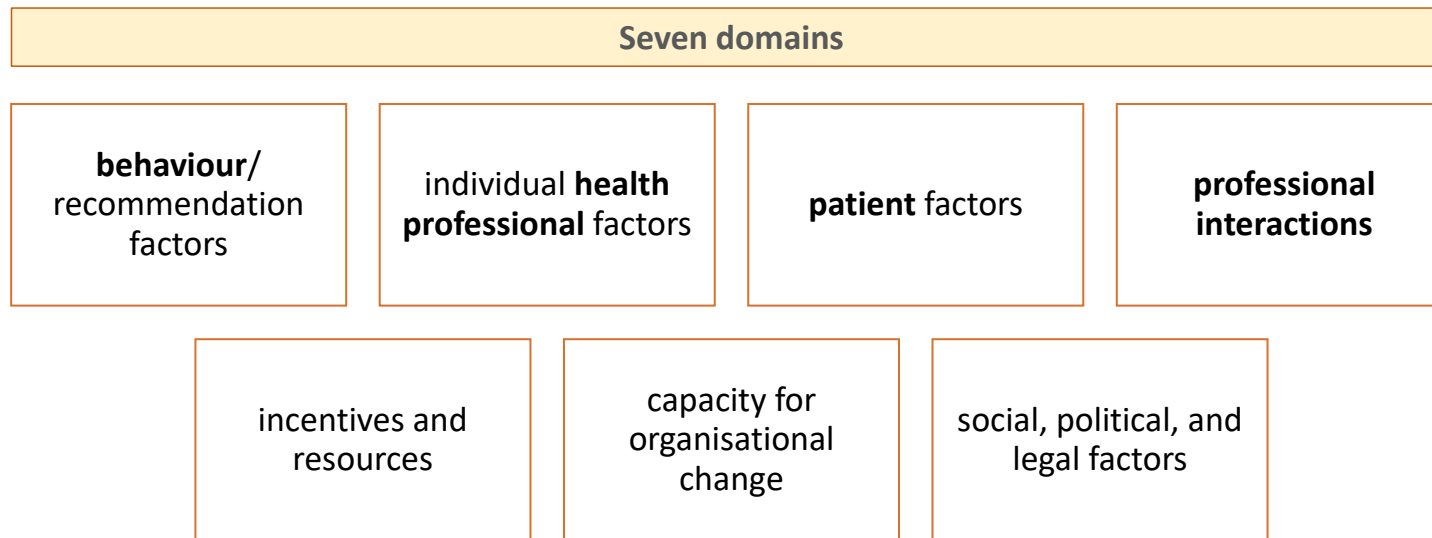
2 – PRIORIZAR OS
“DETERMINANTES”



3 – IDENTIFICAR POTENCIAIS
RECOMENDAÇÕES

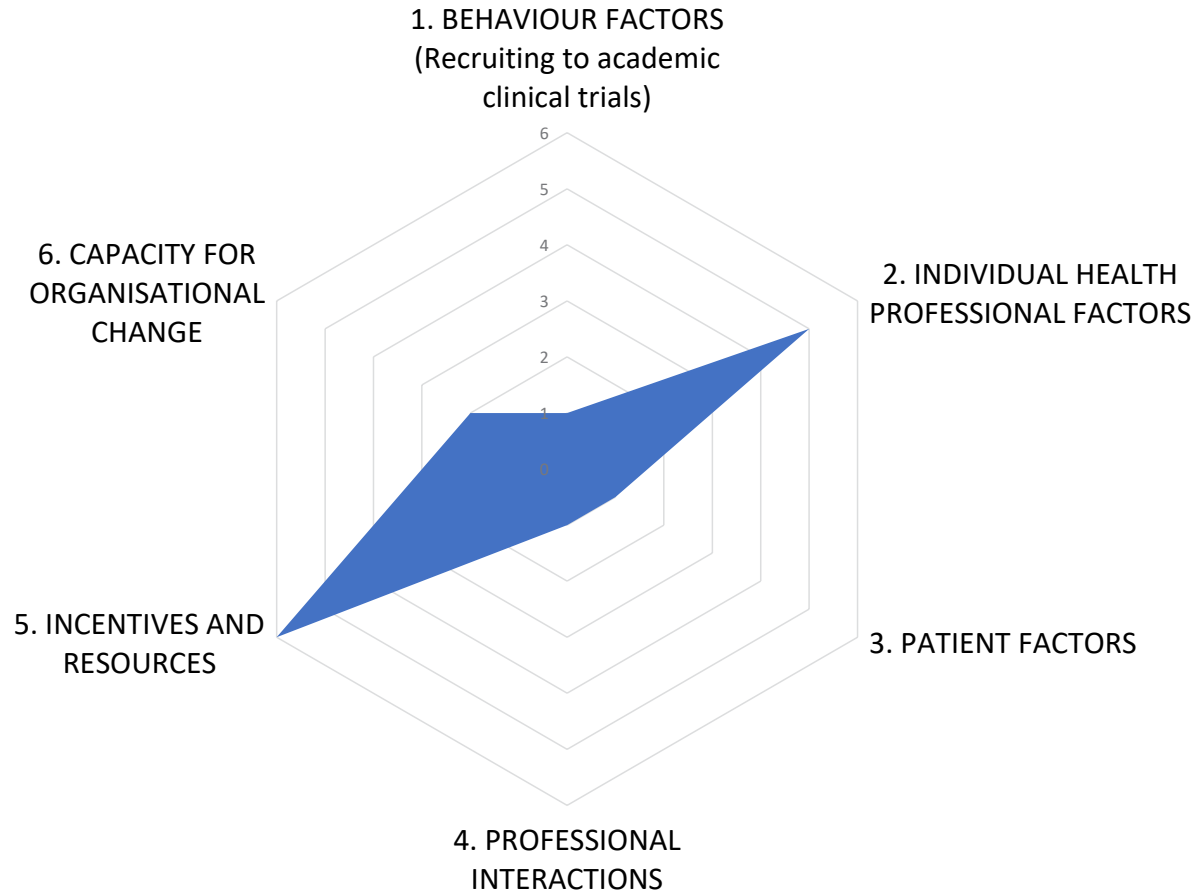
TICD checklist (integrated checklist of determinants of practice, intended as a screening tool)

- Aim of the checklist: to **guide reflection** on **determinants of practice** to **facilitate tailoring interventions**.
- 'Determinants of practice': factors that might prevent or enable healthcare improvements. These **include factors that can be modified** and **factors that can be used to gauge the potential** for achieving change.



Flottorp, S.A., Oxman, A.D., Krause, J. *et al.* A checklist for identifying determinants of practice: A systematic review and synthesis of frameworks and taxonomies of factors that prevent or enable improvements in healthcare professional practice. *Implementation Sci* 8, 35 (2013). <https://doi.org/10.1186/1748-5908-8-35>

Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)



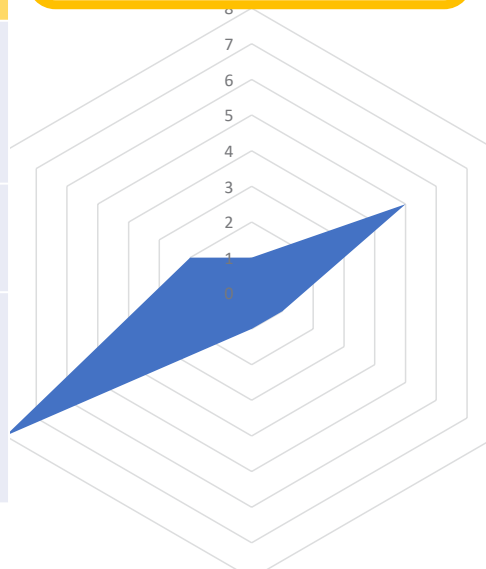
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TICD checklist:

Determinants	Definitions
Compatibility	The extent to which the recommended behaviour fits with current practices
Effort	The amount of effort required to change or adhere
Observability	The degree to which benefits of the recommended behaviour are visible ("Are the benefits of adhering to the recommendation observable?")

1. BEHAVIOUR FACTORS (Recruiting to academic clinical trials)

➤ Narrow eligibility criteria (leading to limited access to and recruitment of people with the disease)



Questões:

1 – Identificam Barreiras adicionais (ou facilitadores)?

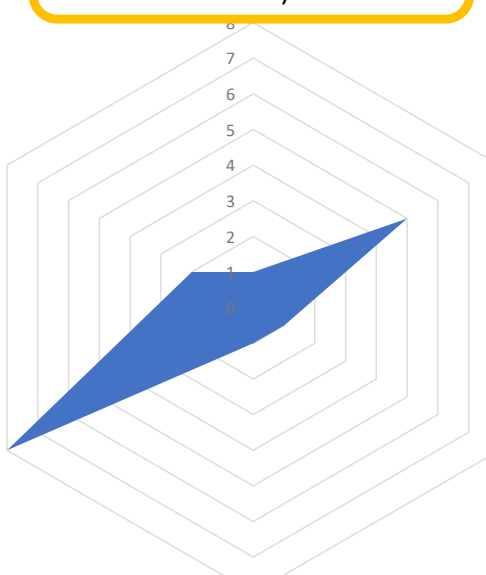
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Estratégias de implementação

- Creating **multicenter national networks** to facilitate patient referrals for clinical trial participation.
- **Leveraging electronic health records** to identify eligible patients more effectively.

1. BEHAVIOUR FACTORS (Recruiting to academic clinical trials)



Impact score:

Scoring of the likely impact:

- 3 = major reduction in
- 2 = moderate reduction in
- 1 = minor reduction in adherence
- +1 = minor increase in adherence
- +2 = moderate increase in adherence
- +3 = major increase in adherence

Questões:

- 2 – Potencial impacto da resolução das Barreiras para ‘resolver o problema’ (**Impact score**)
- 3 – Potenciais estratégias para endereçar esta Barreira

Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)

TICD checklist:

2. INDIVIDUAL HEALTH PROFESSIONAL FACTORS

2.1 Knowledge and skills

Domain knowledge

Awareness and familiarity with the recommendation

Knowledge about own practice

Skills needed to adhere

2.2 Cognitions (including attitudes)

Agreement with the recommendation

Attitudes towards RCTs in general

Expected outcome

Intention and motivation

Self-efficacy

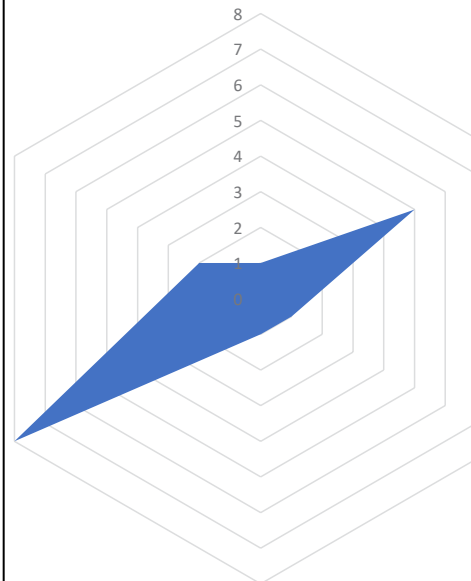
Emotions

2.3 Professional behaviour

Nature of the behaviour

Capacity to plan change

Self-monitoring or feedback



2. INDIVIDUAL HEALTH PROFESSIONAL FACTORS

- Lack of **experience** and **guidance**.
- Expectation to use Investigational Medicinal Products from the shelf within the context of an academic clinical trial.
- **Underappreciation of added value** of engagement of the PT network with international networks
- **Lack of acknowledgment of academic research's potential** by investigators
- Lack of responsiveness to feasibility assessments and recruitment issues (potentially due to limited resources and/or insufficient investment or prioritization of academic trials)

Questões:

1 – Identificam Barreiras adicionais (ou facilitadores)?

Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)

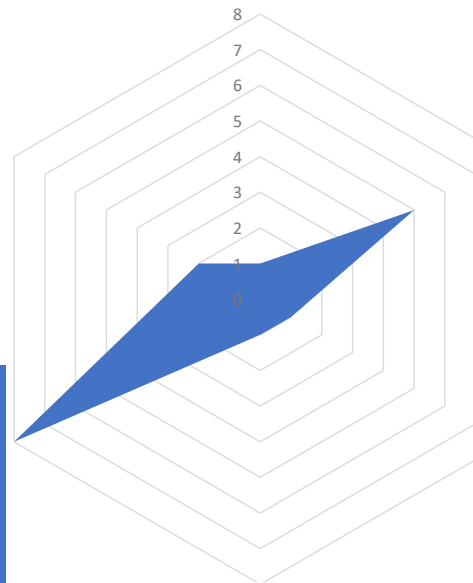
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Questões:

2 – Potencial impacto da resolução desta Barreira para ‘resolver o problema’ (Impact score)



2. INDIVIDUAL HEALTH PROFESSIONAL FACTORS

- Lack of experience and guidance.
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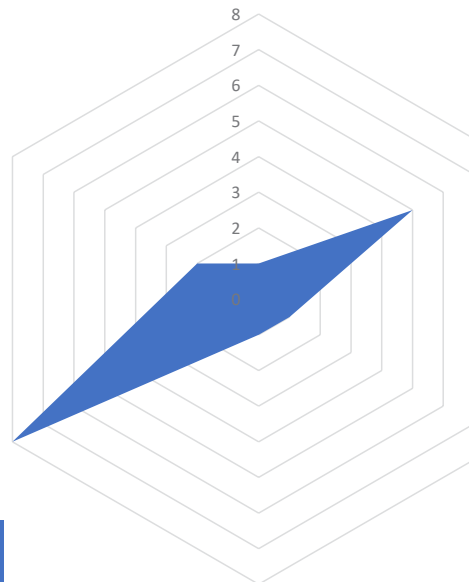


Estratégias de implementação

- Providing **guidance and support** for **funding acquisition** and **development of grant proposals**.
- Incorporating **decentralized clinical trial elements** to increase recruitment potential.

Questões:

3 – Potenciais estratégias para endereçar esta Barreira



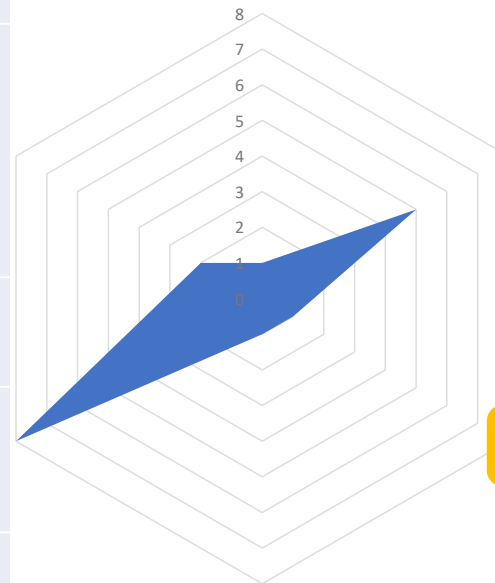
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Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)

TICD checklist:

Determinants	Definitions
Patient needs	Real or perceived needs and demands of the patient
Patient beliefs and knowledge	Patients' beliefs or knowledge or ability to learn, or the targeted healthcare professionals' ability or perceived ability to inform or teach patients necessary knowledge and skills
Patient preferences	Patients' values in relationship to professional values or those in the recommendation
Patient motivation	The targeted healthcare professionals' ability or perceived ability to motivate patients to adhere
Patient behaviour	Patient behaviours that motivate or demotivate adherence with the recommendation



3. PATIENT FACTORS

- Limited patient's access to adequate information, leading to limited access and recruitment of people with the disease

Questões:

1 – Identificam Barreiras adicionais (ou facilitadores)?

Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)

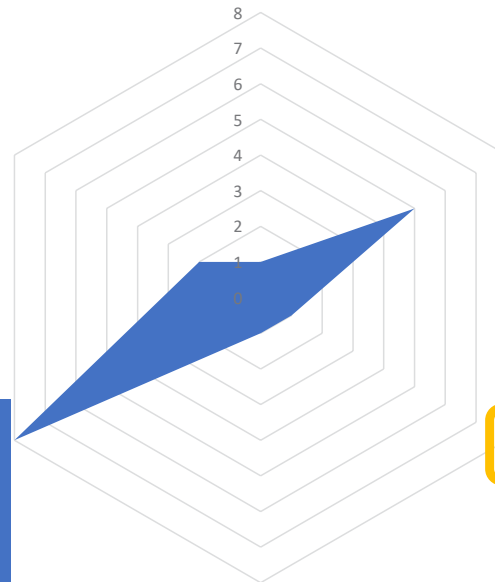


- Improve **effective communication** with patients
- Enhance **health literacy** about the benefits and risks of clinical trial participation

Questões:

2 – Potencial impacto da resolução desta Barreira para 'resolver o problema' (**Impact score**)

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3. PATIENT FACTORS

- Limited patient's access to adequate information, leading to limited access and recruitment of people with the disease

Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)

TICD checklist:

Determinants	Definitions
Communication and influence	The extent to which the targeted healthcare professionals' adherence is influenced by professional opinions and communication
Team processes	The extent to which professional teams or groups have the skills needed to adhere and interact in ways that facilitate or hinder adherence ("What skills do targeted professional teams or groups need to have? Do they have those skills? Do they interact in ways that facilitate or hinder adherence with the recommendation?)
Referral processes	Processes for transferring patients and communication between different levels of care, between health and social services, and between the targeted healthcare professionals and targeted patients

Questões:

1 – Identificam Barreiras adicionais (ou facilitadores)?

4. PROFESSIONAL INTERACTIONS

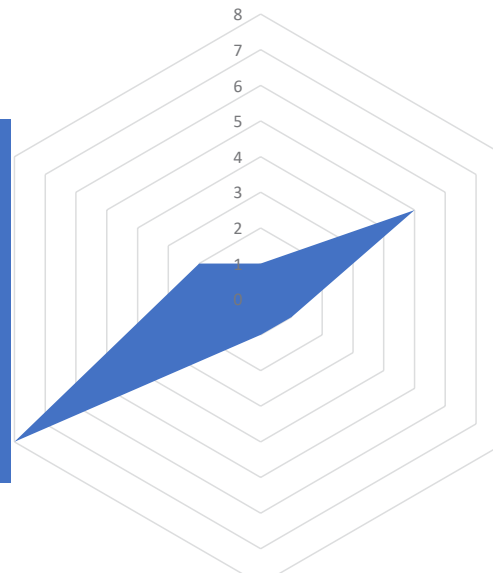
➤ Lack of engagement of the PT network with international networks (potentially due to an underappreciation of added value)

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4. PROFESSIONAL INTERACTIONS

- Lack of engagement of the PT network with international networks (potentially due to an underappreciation of added value)

Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)

TICD checklist:

Determinants	Definitions
Availability of necessary resources	The extent to which the resources that are needed to adhere are available
Financial incentives and disincentives	The extent to which patients, individual health professionals and organisations have financial incentives or disincentives to adhere
Nonfinancial incentives and disincentives	The extent to which patients, individual health professionals and organisations have nonfinancial incentives or disincentives to adhere
Information system	The extent to which the information system facilitates or hinders adherence
Quality assurance and patient safety systems	The extent to which existing quality assurance or patient safety systems facilitate or hinder adherence
Continuing education system	The extent to which the continuing education system facilitates or hinders adherence
Assistance for clinicians	The extent to which clinicians have the assistance they need to adhere

5. INCENTIVES AND RESOURCES

- Limited **availability of screening procedures** (e.g., NGS) and/or treatments as part of the standard of care.
- Insufficient **time** dedicated to research.
- **Low patient compensation per enrollee** (potentially linked to both a lack of reimbursement for patients' travel expenses and inadequate compensation for hospital costs).
- **Insufficient investment or prioritization of academic trials** leading to lack of responsiveness to feasibility assessments and recruitment issues.
- **Lack of access to innovative treatments** in academic clinical trials.
- Limited funding opportunities.

Questões:

1 – Identificam Barreiras adicionais (ou facilitadores)?

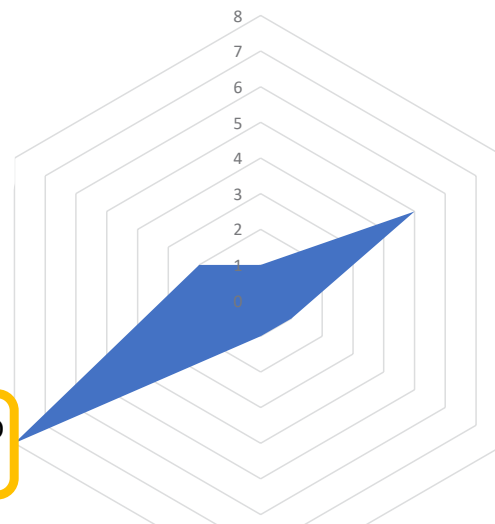
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5. INCENTIVES AND RESOURCES



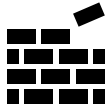
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- Lack of access to innovative treatments in academic clinical trials
- Limited funding opportunities.

Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)



6. CAPACITY FOR ORGANISATIONAL CHANGE

- Insufficient prioritization of academic trials leading to lack of responsiveness to feasibility assessments and recruitment issues
- Increased acknowledgment of academic research's potential by institutions
- Recruitment support through the forthcoming Portugal Clinical Studies platform (anticipated Q1 2025).
- Implementation of autonomous management in health institutions (Despacho nº1739/2024, 14 Fevereiro, 2024).



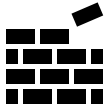
Questões:

1 – Identificam Barreiras adicionais (ou facilitadores)?

TICD checklist:

Determinants	Definitions
Mandate, authority, accountability	The mandate, authority and accountability for making necessary changes ("What organisational changes are needed and who has the mandate and authority to make necessary changes? Who is accountable, to whom and how?")
Capable leadership	The extent to which clinical leaders or managers are capable of making necessary changes ("What changes require leadership or management? Are there leaders or managers with the necessary capacity (including knowledge, project management, other necessary skills and time)? Are they engaged and is their leadership or management style suitable?")
Relative strength of supporters and opponents	
Regulations, rules, policies	The extent to which organisational regulations, rules or policies facilitate or hinder necessary changes
Priority of necessary change	The relative priority given to making necessary changes
Monitoring and feedback	
Assistance for organisational changes	
Monitoring and feedback	The extent to which monitoring and feedback are needed at organisational level and available to sustain necessary changes (including evaluations of improvement programs)
Assistance for organisational changes	The extent to which external support is needed and available for necessary changes

Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)



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Questões:

2 – Potencial impacto da resolução destas Barreira para 'resolver o problema' (**Impact score**)

3 – Potenciais estratégias para endereçar esta Barreira

Barriers shared by stakeholders previous to the meeting, organised following the TICD checklist (N=16)

TICD checklist: 7. SOCIAL, POLITICAL AND LEGAL FACTORS

Determinants	Definitions
Economic constraints on the health care budget	Limits on the total healthcare budget or its growth
Contracts	The extent to which contracts may affect implementation of necessary changes
Legislation	The extent to which legislation may affect implementation of necessary changes
Payer or funder policies	The extent to which payer or funder policies may affect implementation of necessary changes
Malpractice liability	The extent to which malpractice liability may affect implementation of necessary changes
Influential people	The extent to which influential people may affect implementation of necessary changes
Political stability	The extent to which political stability may affect implementation of necessary changes

- Recruitment support through the forthcoming Portugal Clinical Studies platform (anticipated Q1 2025).
- Implementation of autonomous management in health institutions (Despacho nº1739/2024, 14 Fevereiro, 2024).



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Questões:

- 1 – Identificam Barreiras (ou facilitadores) neste tópico?
- 2 – Potencial impacto da resolução destas Barreira para ‘resolver o problema’ (Impact score)
- 3 – Potenciais estratégias para endereçar esta Barreira

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Próximos passos

28 Out 2024

