

AMP

ACTA
MÉDICA
PORTUGUESA

A Revista Científica da Ordem dos Médicos



1 | 26

Número 1
Série II
Lisboa

Volume 39
Janeiro 2026
Publicação Mensal

Director: Bastonário da Ordem dos Médicos, **Carlos Cortes**

Director-Adjunto e Editor: **Tiago Villanueva**

Corpo Editorial

Editor-Chefe: **Tiago Villanueva**, Acta Médica Portuguesa. Lisboa. Portugal.

Editor-Chefe Adjunto: **Helena Donato**, Centro Hospitalar e Universitário de Coimbra. Coimbra. Portugal.

Editores Associados: **Bernardo Gomes**, Unidade de Saúde Pública Entre Douro e Vouga I. Santa Maria da Feira. Portugal.; **Edgar Mesquita**, Instituto de Saúde Pública da Universidade do Porto. Porto. Portugal.; **Filipe Martinho**, Hospital Prof. Doutor Fernando Fonseca. Amadora. Portugal.; **Helena Gouveia**, Fundação Champalimaud. Lisboa. Portugal.; **Henrique Alexandrino**, Centro Hospitalar e Universitário de Coimbra. Coimbra. Portugal.; **João Carlos Ribeiro**, Centro Hospitalar e Universitário de Coimbra. Coimbra. Portugal.; **Maria João Lobão**, Hospital de Cascais. Cascais. Portugal.; **Marina Pinheiro**, Unidade de Saúde Pública ACES Cávado III - Barcelos/Espesinde. Braga. Portugal.; **Tiago Torres**, Centro Hospitalar Universitário do Porto. Porto. Portugal.

Coordenação Editorial: Carla de Sousa **Assistente Editorial:** Bruna Duarte **Editor de Imagem:** Rui Matos **Open Journal System:** José Carona Carvalho **Webmaster:** Cloudpro Lda. **Tradutor:** Miguel Fontes.

Editores Emeriti: Alberto Galvão Teles (1978 – 1987), F. Veiga Fernandes (1987 – 1993), A. Sales Luís (1993 – 1996), Carlos Ribeiro (1996 – 1998), J. Germano Sousa (1999 – 2004), Pedro Nunes (2005 – 2010), Rui Tato Marinho (2011 – 2016), José Manuel Silva (2017).

Propriedade: Ordem dos Médicos (NIPC 500 984 492)

Sede do Editor / Redação: Av. Almirante Gago Coutinho, 151. 1749-084 Lisboa, Portugal. Tel: +351 21 151 71 00 E-mail: secretariado@actamedicaportuguesa.com
ISSN:0870-399X | e-ISSN: 1646-0758

Assinaturas: Nacional: 300 Euros; Internacional: 350 Euros.

AMP39(1) - Janeiro de 2026



Registo: Inscrito na Entidade Reguladora para a Comunicação Social com o N.º 106 369

Depósito legal: 20 957/88

Estatuto Editorial: <http://www.actamedicaportuguesa.com/normas-de-publicacao>

Open Access: A Acta Médica Portuguesa é licenciada sob uma Licença Creative Commons - Attribution Non-Commercial (CC BY NC).

Conselho Científico

Álvaro Cohen

Representante do Colégio da Competência de Ecografia Obstétrica Diferenciada da Ordem dos Médicos. Lisboa. Portugal.

Ana Isabel Santos

Representante do Colégio de Especialidade de Medicina Nuclear da Ordem dos Médicos. Lisboa. Portugal.

Ana Rita Cravo

Representante do Colégio da Competência de Medicina Farmacêutica da Ordem dos Médicos. Lisboa. Portugal.

António Franklin Ramos

Representante do Colégio da Competência de Gestão dos Serviços de Saúde da Ordem dos Médicos. Lisboa. Portugal.

António Gandra d'Almeida

Representante do Colégio da Competência de Medicina Militar da Ordem dos Médicos. Lisboa. Portugal.

António Jorge Silva

Representante do Colégio da Competência de Hidrologia Médica da Ordem dos Médicos. Lisboa. Portugal.

António Marques da Silva

Representante do Colégio da Especialidade de Anestesiologia da Ordem dos Médicos. Lisboa. Portugal.

Armando Mansilha

Representante do Colégio de Especialidade de Angiologia e Cirurgia Vascular da Ordem dos Médicos. Lisboa. Portugal.

Carlos Sottomayor

Presidente do Colégio de Especialidade de Oncologia da Ordem dos Médicos. Lisboa. Portugal.

Catarina Aguiar Branco

Representante do Colégio de Especialidade de Medicina Física e de Reabilitação da Ordem dos Médicos. Lisboa. Portugal.

Daniel Beirão

Representante do Colégio da Competência de Peritagem Médica da Segurança Social da Ordem dos Médicos. Lisboa. Portugal.

Duarte Nuno Vieira

Representante do Colégio da Competência de Avaliação do Dano na Pessoa da Ordem dos Médicos. Lisboa. Portugal.

Eduardo Netto

Representante do Colégio da Especialidade de Radioncologia da Ordem dos Médicos. Lisboa. Portugal.

Fernando Lopes

Representante do Colégio da Competência de Codificação Clínica da Ordem dos Médicos. Lisboa. Portugal.

Filomena Botelho

Representante do Colégio da Competência de Patologia Experimental da Ordem dos Médicos. Lisboa. Portugal.

Francisco Esteves

Representante do Colégio de Especialidade de Medicina Intensiva da Ordem dos Médicos. Lisboa. Portugal.

Graça Mesquita

Representante do Colégio da Competência de Medicina da Dor da Ordem dos Médicos. Lisboa. Portugal.

Isabel Fragata

Representante do Colégio de Especialidade de Neuroradiologia da Ordem dos Médicos. Lisboa. Portugal.

Isabel Lima dos Santos

Representante do Colégio da Competência de Acupuntura Médica da Ordem dos Médicos. Lisboa. Portugal.

Isabel Lúzeiro

Representante do Colégio de Especialidade de Neurologia da Ordem dos Médicos. Lisboa. Portugal.

Joana Patrícia Tavares Ferreira

Representante do Colégio de Especialidade de Oftalmologia da Ordem dos Médicos. Lisboa. Portugal.

João Mariano Pego

Representante do Colégio de Especialidade de Patologia Clínica da Ordem dos Médicos. Lisboa. Portugal.

João Vítor Pina Alves

Representante do Colégio de Especialidade de Dermatovenereologia da Ordem dos Médicos. Lisboa. Portugal.

João Guerra da Costa

Representante do Colégio da Especialidade de Farmacologia Clínica da Ordem dos Médicos. Lisboa. Portugal.

José Durão

Representante do Conselho Nacional do Médico Interno da Ordem dos Médicos. Lisboa. Portugal.

José G. Merino

Georgetown University Medical Center. Washington. Estados Unidos da América.

José Manuel Mira Mendes Furtado

Representante do Colégio de Especialidade de Ginecologia e Obstetria da Ordem dos Médicos. Lisboa. Portugal.

José Miguens

Presidente do Colégio da Especialidade de Neurocirurgia da Ordem dos Médicos. Lisboa. Portugal.

José Neves

Representante do Colégio de Especialidade de Cirurgia Cardiorádica da Ordem dos Médicos. Lisboa. Portugal.

José Pinho Marques

Presidente do Colégio da Especialidade de Medicina Desportiva da Ordem dos Médicos. Lisboa. Portugal.

Lia Sousa Fernandes

Representante do Colégio da Competência de Geriatria da Ordem dos Médicos. Lisboa. Portugal.

Lino Gonçalves

Representante do Colégio de Competência de Sexologia da Ordem dos Médicos. Lisboa. Portugal.

Lisa Vicente

Representante do Colégio de Especialidade de Cardiologia da Ordem dos Médicos. Lisboa. Portugal.

Luciana Baêre de Faria Ricca Gonçalves

Representante do Colégio de Especialidade de Imuno-hemoterapia da Ordem dos Médicos. Lisboa. Portugal.

Luís Cadinha

Representante do Colégio de Especialidade de Saúde Pública da Ordem dos Médicos. Lisboa. Portugal.

Luís Lopes

Representante do Colégio de Especialidade de Gastroenterologia da Ordem dos Médicos. Lisboa. Portugal.

Luís Monteiro

Representante do Colégio de Especialidade de Urologia da Ordem dos Médicos. Lisboa. Portugal.

Manuel Carlos Loureiro de Lemos

Representante do Colégio de Especialidade de Endocrinologia e Nutrição da Ordem dos Médicos. Lisboa. Portugal.

Manuela Silva

Representante do Colégio de Especialidade de Psiquiatria da Ordem dos Médicos. Lisboa. Portugal.

Maria José Costa Almeida

Representante do Colégio da Especialidade de Medicina do Trabalho da Ordem dos Médicos. Lisboa. Portugal.

Maria da Graça de Figueiredo Vilar

Representante do Colégio da Competência de Adictologia Clínica da Ordem dos Médicos. Lisboa. Portugal.

Marta Janeiro da Costa Dias

Institute of Cancer Research / University College London Hospitals. London. United Kingdom.

Matthew Clarke

Institute of Cancer Research / University College London Hospitals. London. United Kingdom.

Miguel Vilares

Representante do Colégio de Especialidade de Maxilo-Facial da Ordem dos Médicos. Lisboa. Portugal.

Nelson José de Sousa Pereira

Representante do Colégio da Competência de Emergência Médica da Ordem dos Médicos. Lisboa. Portugal.

Nuno Diogo

Representante do Colégio de Especialidade de Ortopedia da Ordem dos Médicos. Lisboa. Portugal.

Nuno Maria Trigueiros da Silva Cunha

Representante do Colégio de Especialidade de Otorrinolaringologia da Ordem dos Médicos. Lisboa. Portugal.

Paula Maria Broeiro Gonçalves

Representante do Colégio de Especialidade de Medicina Geral e Familiar da Ordem dos Médicos. Lisboa. Portugal.

Paulo Santos

Representante do Colégio de Especialidade de Psiquiatria da Infância e Adolescência da Ordem dos Médicos. Lisboa. Portugal.

Raquel Tavares

Representante do Colégio de Especialidade de Doenças Infecciosas da Ordem dos Médicos. Lisboa. Portugal.

Ricardo Veiga

Representante do Colégio de Especialidade de Anatomia Patológica da Ordem dos Médicos. Lisboa. Portugal.

Rui Duarte Castro Moreira

Representante do Colégio de Especialidade de Estomatologia da Ordem dos Médicos. Lisboa. Portugal.

Sofia Vidigal e Almada

Representante do Colégio da Competência de Medicina Aeronáutica da Ordem dos Médicos. Lisboa. Portugal.

Susana de Sousa

Representante do Colégio da Competência de Medicina do Sono da Ordem dos Médicos. Lisboa. Portugal.

Susana Tavares

Representante do Colégio da Especialidade de Medicina Legal da Ordem dos Médicos. Lisboa. Portugal.

Teresa Magalhães

Faculdade de Medicina. Universidade do Porto. Porto. Portugal.

Unidades de Cuidados Saúde Primários Universitárias: Do Sonho à Realidade

Academic Primary Care Units: From Dream to Reality

Gil CORREIA ^{1,2,3}, António PEREIRA ^{4,5,6}, Cláudia BULHÕES ^{7,8,9}, Conceição OUTEIRINHO ^{10,11}, Filipe PRAZERES ^{12,13,14}, Inês ROSENDO ^{1,15}, José Pedro ANTUNES ^{16,17,18}, Luís MONTEIRO ^{17,18,19}, Nuno JACINTO ^{20,21}, Paula BROEIRO-GONÇALVES ^{22,23}, Paulo SANTOS ⁴, Pedro SIMÕES ^{24,25}, Raquel RESENDES MARTINS^{26,27}, Rubina CORREIA^{28,29}, Tiago MARICOTO ^{30,31}, Luiz Miguel SANTIAGO ^{1,15}
Acta Med Port 2026 Jan;**39**(1):1-7 • <https://doi.org/10.20344/amp.23593>

Palavras-chave: Cuidados de Saúde Primários; Médicos de Família; Portugal; Prestação Integrada de Cuidados de Saúde; Programas Nacionais de Saúde; Reforma dos Serviços de Saúde; Serviço Nacional de Saúde/organização e administração

Keywords: Delivery of Health Care, Integrated; Health Care Reform; National Health Programs; Physicians, Family; Portugal; Primary Health Care; State Medicine/organization & administration

INTRODUÇÃO

A generalização do modelo de gestão do Serviço Nacional de Saúde português (SNS) em unidades locais de saúde (ULS), em 2024, implicou a fusão e extinção de mais de 50 instituições. Entre estas, encontram-se agrupamentos de centros de saúde (ACES), administrações regionais de saúde (ARS) e hospitais do setor público administrativo (instituições hospitalares públicas, incluindo as do setor empresarial do estado) no que foi apresentada como a “maior transformação do SNS desde a sua criação”.¹⁻³ Esta reforma agregou os serviços públicos de saúde de uma dada região geográfica numa única instituição, pela

integração vertical (modelo de gestão/organização dos Cuidados de Saúde em que uma única instituição congrega os diferentes níveis de cuidados prestados - desde os cuidados preventivos na comunidade, primários, hospitalares, continuados e paliativos).^{2,4,5} A integração dos cuidados de saúde primários (CSP) de forma abrupta, sem atender às especificidades da estrutura e expectativas dos profissionais, resultou em desafios organizacionais.⁶

Este modelo, financiado por capitação, coerente com a integração vertical, pretende privilegiar os cuidados centrados na pessoa, dado que a mesma ULS é responsável por

1. Clínica Universitária de Medicina Geral e Familiar. Faculdade de Medicina. Universidade de Coimbra. Coimbra. Portugal.
2. Centro de Inovação em Biomedicina e Biotecnologia (CIBB). Universidade de Coimbra. Coimbra. Portugal.
3. Unidade de Saúde Familiar CelaSaúde. Unidade Local de Saúde de Coimbra. Coimbra. Portugal.
4. MEDCIDS. RISE-Health@RISE. Faculdade de Medicina. Universidade do Porto. Porto. Portugal.
5. Departamento de Ciências Médicas. Universidade de Aveiro. Aveiro. Portugal.
6. Unidade de Saúde Familiar Prelada. Unidade Local de Saúde de Santo António. Porto. Portugal.
7. Escola de Medicina. Universidade do Minho. Braga. Portugal.
8. Unidade de Saúde Familiar Vida+. Unidade Local de Saúde Braga. Braga. Portugal.
9. Instituto de Investigação em Ciências da Vida e Saúde. Universidade do Minho. Braga. Portugal.
10. Instituto de Ciências Biomédicas Abel Salazar (ICBAS). Universidade do Porto. Porto. Portugal.
11. Unidade de Saúde Familiar Barão de Nova Sintra. Unidade Local de Saúde de São João. Porto. Portugal.
12. Departamento de Ciências Médicas. Faculdade de Ciências da Saúde. Universidade da Beira Interior. Covilhã. Portugal.
13. Unidade de Saúde Familiar Beira Ria. Gafanha da Nazaré. Portugal.
14. RISE-Health. Departamento de Medicina da Comunidade, Informação e Decisão em Saúde. Faculdade de Medicina. Universidade do Porto. Porto. Portugal.
15. Unidade de Saúde Familiar Coimbra Centro. Unidade Local de Saúde de Coimbra. Coimbra. Portugal.
16. Unidade de Saúde Familiar Arte Nova. Unidade Local de Saúde da Região de Aveiro. Aveiro. Portugal.
17. Departamento de Ciências Médicas. Universidade de Aveiro. Aveiro. Portugal.
18. Centro Académico Clínico Egas Moniz Health Alliance. Universidade de Aveiro. Aveiro. Portugal.
19. USF Esgueira +. Unidade Local de Saúde Região de Aveiro. Aveiro. Portugal.
20. Associação Portuguesa de Medicina Geral e Familiar. Lisboa. Portugal.
21. Unidade Local de Saúde Alentejo Central. Évora. Portugal.
22. NOVA Medical School. Universidade NOVA de Lisboa. Lisbon. Portugal.
23. Unidade de Cuidados de Saúde Personalizados Olivais. Unidade Local de Saúde S. José. Lisboa. Portugal.
24. Faculdade Ciências da Saúde. Universidade da Beira Interior. Covilhã. Portugal.
25. Unidade de Cuidados de Saúde Personalizados Fundão. Unidade Local de Saúde Cova da Beira. Covilhã. Portugal.
26. Centro de Saúde da Ilha de São Miguel. Unidade de Saúde da Ilha de São Miguel. Ponta Delgada. Portugal.
27. Faculdade de Ciências e Tecnologia. Universidade dos Açores. Ponta Delgada. Portugal.
28. Unidade Local de Saúde Algarve. Faro. Portugal.
29. Faculdade de Medicina. Universidade do Porto. Porto. Portugal.
30. Centro de Investigação em Ciências da Saúde (CICS-UBI). Universidade da Beira Interior. Covilhã. Portugal.
31. Unidade de Saúde Familiar Beira Ria. Unidade Local de Saúde de Aveiro. Ilhavo. Portugal.

✉ **Autor correspondente:** Gil Correia. gil.correia@gmail.com

Revisto por/Reviewed by: Patrícia Borges Fernandes  e Daniel Beirão .

Recebido/Received: 27/06/2025 - **Aceite/Accepted:** 15/09/2025 - **Publicado Online/Published Online:** 31/10/2025 - **Publicado/Published:** 02/01/2026
Copyright © Ordem dos Médicos 2026



todo o contínuo do processo de cuidados.⁷ As vantagens apontadas incluem aumento de eficiência, qualidade de acesso, promoção de cuidados preventivos e desenvolvimento de percursos clínicos de cuidados integrados.^{2-4,8}

Apesar de se prever um aumento da proximidade entre o nível da prestação de cuidados e a gestão, a sua implementação encontrou constrangimentos e desencadeou resistência dos profissionais.^{5,6} Dadas as assimetrias, persistem dúvidas relativamente ao seu financiamento, em particular nas ULS que incluem centros universitários, o que motivou a constituição de um grupo de trabalho, em 2024.^{5,6,9,10}

A nomeação do grupo foi alvo de críticas por não incluir representantes de algumas das partes interessadas. O relatório final incluiu a proposta de criação de novas camadas na governação das ULS, não avançando propostas estruturais mais aprofundadas. Além disso, não incluiu referências aos CSP, com exceção da posição da Associação Portuguesa de Medicina Geral e Familiar (APMGF).¹¹

No presente artigo propomos uma nova forma de organização dos CSP nas ULS – particularmente as que incluem centros universitários – complementar à resposta existente, pela criação de unidades de cuidados de saúde primários universitários.

OS CUIDADOS DE SAÚDE PRIMÁRIOS NAS UNIDADES LOCAIS DE SAÚDE

Os CSP portugueses foram inovadores no seio da administração pública por integrarem um modelo de pagamento por desempenho (P4P), desde a reforma em 2005.^{5,12,13} Desde então, os CSP assentam maioritariamente em pequenas unidades multiprofissionais com autonomia organizativa, funcional e técnica – as unidades de saúde familiar (USF) criadas por adesão voluntária dos profissionais, com uma matriz comum e objetivos de desempenho bem definidos e contratualizados anualmente.^{5,14} Os cuidados hospitalares têm uma organização distinta apesar do impulso recente na criação de centros de responsabilidade integrada, que integram P4P.^{15,16}

A integração vertical dos cuidados promove a eficiência pela criação de valor em saúde, e obriga ao reforço da capacidade dos CSP e do seu enquadramento legal. O modelo ULS mantém a centralidade na pessoa, continuando os CSP como pilar central e principal porta de entrada do cidadão no sistema de saúde, com uma importância crucial pela prevenção e promoção da saúde e pela coordenação de cuidados com impacto na eficiência, apesar do receio dos profissionais de saúde no seguimento de uma orientação hospitalocêntrica.^{2,5,6,12,17}

Os CSP promovem a equidade e o acesso a cuidados de saúde, eficazes, eficientes e capazes de criar valor em saúde.¹⁸⁻²¹ Desta forma, a aposta nos CSP permite mitigar

os riscos de um financiamento global das ULS por capitação, pelos incentivos que podem desencorajar a prestação de determinados serviços e cuidados.^{13,17,22,23}

CUIDADOS DE SAÚDE PRIMÁRIOS E O MODELO UNIDADE DE SAÚDE FAMILIAR

A integração dos CSP nas ULS pode proporcionar vantagens ao sistema.¹² É essencial, no entanto, garantir a preservação da identidade e autonomia do exercício, assegurando uma gestão que reflete as necessidades específicas dos utentes. A satisfação das expectativas, incentivos e reconhecimento do trabalho, também em seu mérito são, por outro lado, fundamentais para a captação e manutenção de recursos humanos.

Importa reconhecer que o âmbito dos CSP não se esgota nas USF –unidades prestadoras de cuidados de saúde direcionadas ao cumprimento de objetivos específicos importantes, mas parcelares nas necessidades de saúde da população.²⁴ Num modelo de P4P, “obtemos o que medimos”, o que destaca a importância de desenhar objetivos apropriados, medidos por indicadores rigorosos que realmente reflitam a qualidade do serviço prestado. No entanto, este modelo pode ter limitado o desenvolvimento de outras dimensões dos CSP e criado um custo de oportunidade relativamente a outros modelos de desenvolvimento. Também, o carácter voluntário de adesão à USF pode ter promovido o antagonismo entre equipas, a desigualdade de recursos humanos, e criado uma maior assimetria entre as USF recém-criadas e as unidades de cuidados de saúde personalizadas (UCSP), herdeiras dos antigos centros de saúde.²⁴

Neste sentido, devem ser discutidas propostas alternativas de oferta de serviços abrangentes que valorizem o trabalho dos profissionais de saúde, considerando a complexidade e a diversidade das atividades desempenhadas.^{11,25}

LIMITAÇÕES DAS UNIDADES DE SAÚDE FAMILIAR

A realidade atual é de dispersão de práticas e organização das USF.²⁶ Contrariamente à ideia inicial de uma estrutura leve e adaptável, as USF têm vindo a revelar várias limitações de flexibilidade laboral e de acessibilidade centrada na pessoa,²⁷ com impacto na insatisfação dos profissionais e dificuldade de retenção de recursos humanos. Por outro lado, não tem existido um estímulo à participação no ensino, em atividades de investigação e desenvolvimento ou na formação e capacitação profissional, por exemplo, pela progressão em ciclos avançados de estudos. Estas atividades devem ser protegidas e incentivadas, sem prejuízo para o profissional ou para a equipa multiprofissional.

São conhecidas as barreiras à investigação, como a falta de tempo, de financiamento, de infraestruturas adequadas, o excesso de burocracia e a escassa valorização

profissional.^{28,29} A contratualização em 2017 propunha incluir a investigação e a atividade científica na avaliação das unidades CSP através do índice de desempenho global, embora sem compensação específica ou redução da carga assistencial, mas até ao momento essas áreas não foram operacionalizadas. Reconhecendo insuficiências do modelo atual na resposta às necessidades das populações, dos profissionais e limitação em investigação e desenvolvimento (I&D), algumas respostas alternativas têm vindo a ser propostas e criadas (Tabela 1). Estas, no entanto, têm apresentado os mesmos desafios das USF e as condicionantes decorrentes do financiamento dirigido e sobrecarga assistencial.

CENTRO DE SAÚDE/UNIDADES DE CUIDADOS DE SAÚDE PRIMÁRIOS UNIVERSITÁRIAS

É premente destacar o papel agregador, holístico, coordenador de cuidados e conciliador com outras atividades dos CSP.

A criação de um centro de saúde/unidade de cuidados de saúde primários universitária, integrada numa ULS como resposta complementar em CSP, poderá promover a articulação entre hospitais universitários, instituições de ensino superior e as demais unidades de CSP, permitindo conciliar a vertente assistencial com o ensino pré e pós-graduado nas diversas profissões dos CSP, investigação, e o desenvolvimento de novas abordagens terapêuticas e organizacionais, baseadas em evidência (Tabela 2). Espera-se destas unidades um papel central na investigação em CSP, nomeadamente pela coordenação ou integração de

Tabela 1 – Modelos alternativos de unidades de cuidados de saúde primários e fase de implementação (secção 1 de 2)

Modelo alternativo	Princípios	Fase atual
Via Verde Almada-Seixal	Modelo inovador que integra uma equipa fixa composta por médicos especialistas em MGF, enfermeiros especialistas e generalistas e assistentes técnicos que assegura a assistência de todos os utentes sem médico de família. Esta equipa coordena e supervisiona um conjunto alargado de profissionais, incluindo médicos aposentados especialistas em MGF, internos de MGF, médicos contratados não especializados, médicos de outras unidades e enfermeiros contratados ou provenientes de outras unidades. Baseia-se na complementaridade de funções e tarefas para garantir uma resposta programada e não programada a uma população superior ao que seria esperado em lista de utente.	Extinta. Limitações de retenção de profissionais levaram à sua evolução para modelo USF (USF Inovar)
Clínica Universitária FMUP	Modelo clínico de prestação de cuidados de saúde nas áreas da Medicina Geral e Familiar, Geriatria, Nutrição Clínica e Psicologia. O financiamento depende da produção, sendo feita uma redistribuição pelos profissionais baseada na produção individual. Garante-se o acesso, a continuidade de cuidados, a globalidade e a coordenação no atendimento dos utentes. Trabalho de equipa garantido pela comunicação entre os profissionais ao nível dos registos clínicos e da integração dos objetivos. Assume a responsabilidade na formação pré e pós-graduada através de estágio clínicos e produção de conhecimento.	Em fase de implementação
USF Arte Nova – adaptação do modelo tradicional	Acesso e personalização: utentes da equipa com gestão por microequipas (consulta aberta da unidade, sistemas de intersubstituição de longa duração, etc.). Adaptação do agendamento à demanda (sazonalidade, ausências, priorização clínica, etc.). Prestação de formação a elementos externos à unidade – Escola USF Arte Nova. Gestão e liderança multiprofissional – grupo de apoio executivo. <i>Task shifting</i> : reajustamento de tarefas (ex.: consultas HTA enfermagem). Cultura organizacional: comunicação positiva, sistemas de registos de ocorrências, motivação e gestão do talento. Formação multidisciplinar continua em <i>softskills</i> e <i>teambuilding</i> . Integração formal para atividades não assistenciais para todos os profissionais.	Implementado
USF Académica (FMUL – Campus de Torres Vedras)	Destina-se a cerca de 10 000 utentes sem médico de família, com capacidade para atingir 17 500 utentes. Resulta de uma parceria entre a FMUL e o Município de Torres Vedras, reforçando os cuidados de saúde primários na região. A USF Académica insere-se num projeto maior que inclui a participação em unidades de investigação clínica e tecnológica, e um papel central na formação pré e pós-graduada de profissionais de saúde, promovendo tempo protegido para estas atividades.	Candidatura a USF Modelo C

Tabela 1 – Modelos alternativos de unidades de cuidados de saúde primários e fase de implementação (secção 2 de 2)

Modelo alternativo	Princípios	Fase atual
Centro de Saúde Académico - Coimbra	Integração da prestação de cuidados de saúde com atividades de ensino e investigação, promovendo a articulação entre prática clínica, academia e inovação. Organização centrada na pessoa, com foco no acesso, continuidade e valor em saúde, especialmente para populações em mobilidade e sem médico de família. Estrutura participativa e flexível, que permite a conciliação das funções assistenciais com a formação e a investigação, assegurada por equipas multiprofissionais dedicadas. Serviços transversais à população e complementares com as USF.	Proposta
Centro de Saúde Universitário de Loulé	Construído de raiz por acordo entre o Município, o Ministério da Saúde, a Faculdade de Medicina e do Algarve Biomedical Center (ABC). "Conjuga inovação, conhecimento e serviço público de Saúde". Integra a USF Lauroé, a UCC Gentes de Loulé, a Unidade de Apoio à Gestão e Direção Clínica dos CSP da ULS Algarve. Inclui uma unidade académica de formação e investigação em cuidados de saúde primários, com espaços dedicados à formação pré e pós-graduada.	A funcionar desde 1 de junho de 2025
Outras experiências UCSP de Alcântara, UCSP Brandoa ou UCSP dos Olivais	Estas são algumas das unidades que inovaram o seu modelo organizativo, contribuindo nos cuidados a utentes sem equipa de saúde baseando-se em trabalho colaborativo multiprofissional, revelando-se um excelente contexto formativo pré e pós-graduado.	Implementadas
Centro de Saúde da Ilha de São Miguel (Açores)	A Unidade de Saúde da Ilha de São Miguel (USISM) integra seis centros de saúde, um por concelho, com direção clínica e de enfermagem autónomas. O Centro de Saúde de Ponta Delgada, integra 44 mil utentes (96% com médico de família) e concentra consultas de Medicina Geral e Familiar, Enfermagem, Nutrição, Psicologia, Saúde Oral, Cessação Tabágica, Paliativos, entre outros. Inclui também serviço de atendimento complementar e urgente. Integra ainda múltiplos grupos de trabalho, comissões de apoio técnico e núcleo de formação e investigação. O protocolo com a Universidade dos Açores possibilita a presença de estudantes de Medicina e Enfermagem em contexto clínico, com profissionais da USISM como docentes ou tutores, promovendo a ligação entre ensino e prática. Existem indicadores definidos a nível regional e contratualizados pela USISM, sendo uma orientação para a atividade realizada.	Em funcionamento

"redes de investigação baseadas na prática clínica" – *practice-based research networks* (PBRN).^{28,30}

Este novo centro de saúde de base universitária será uma unidade de prestação de cuidados de saúde multiprofissionais, personalizados, acessíveis e orientados para os CSP, de base populacional, e com autonomia de gestão definida em estatuto específico. Cumprirá uma carteira básica de serviços alargada, que poderá abranger outros serviços e cuidados adaptados às necessidades locais. Será um exemplo de profissionalismo, de rigor, de qualidade e de ética para os profissionais que forma e para a população que cuida. Terá uma responsabilidade acrescida na formação pré e pós-graduada de profissionais nas áreas da saúde e tempo específico alocado, incluindo as atividades de investigação e desenvolvimento ou como piloto e observatório na aplicação de normas ou orientações clínicas.

A integração destes centros de saúde na lógica das ULS e nas regiões autónomas promoverá o desenvolvimento de estruturas de apoio, como gabinetes dedicados ao suporte das atividades de ensino, investigação e prestação de cuidados multiprofissionais, contribuindo para a criação de

valor em saúde para a pessoa.

O modelo de financiamento deverá incidir sobre a resposta assistencial e a produção académica e científica, funcionando como um incentivo à qualidade e ao desenvolvimento, numa perspetiva colaborativa com outras áreas de conhecimento, como a Psicologia, a Nutrição, a Fisiologia do Desporto e a Sociologia, entre outros.¹⁰

Exemplo da aplicação prática deste modelo é o Centro de Saúde Universitário de Loulé (CSUL), atualmente em funcionamento na ULS Algarve. Este centro constitui o primeiro centro de saúde universitário implementado em Portugal, concebido com o objetivo de integrar cuidados assistenciais, investigação clínica e ensino em contexto real. Integra uma rede de investigação e constituirá uma PBRN que visa articular equipas assistenciais com investigadores académicos, promovendo investigação centrada nas necessidades concretas da população. A unidade dispõe de biblioteca, salas de formação, gabinetes dedicados ao ensino clínico e espaços colaborativos de trabalho. Este modelo local poderá servir de referência para o desenvolvimento de estruturas semelhantes noutras regiões do país.

Tabela 2 – Comparação entre modelos: unidade de saúde familiar atual *versus* unidade de cuidados saúde primários universitária

Âmbito	Características comuns	Características particulares a implementar
Prestação de cuidados	Cuidados médicos e de enfermagem prestados pela equipa nuclear, por acompanhamento em lista de famílias. Intersubstituição garantida na ausência dos profissionais pelos restantes profissionais. Acompanhamento do desenvolvimento organizacional das equipas – grelha DiOr nas áreas da Centralidade no cidadão, organização centrada no cidadão – em termos organizativos e clínicos	Centralidade dos cuidados no cidadão, garantindo a longitudinalidade e acessibilidade de forma flexível. Possibilidade de prestação de cuidados em equipa multiprofissional alargada de forma regular, com integração de respostas específicas. Reforçar o trabalho em equipa com incentivos específicos e transversais para outras respostas em CSP (p. ex.: consultas específicas: atendimento a jovens; consulta de complexidade; paliativos, população sem médico de família, etc.).
Modo de trabalho	Autonomia, responsabilização e trabalho em equipa para resposta a lista de utentes. Tarefas clínicas (saúde infantil e juvenil, saúde da mulher, hipertensão, diabetes <i>mellitus</i> , doença pulmonar obstrutiva crónica, asma, etc.). Horário desenhado para as tarefas dos profissionais e o cumprimento do plano de ação.	Centralidade na pessoa, flexibilidade da resposta considerando o valor em saúde. Modelo multiprofissional com articulação com instituições académicas; trabalho colaborativo com tempo protegido para ensino e investigação; outras atividades (ensino e investigação, novos projetos em CSP, etc.).
Valorização desempenho	Sistema de indicadores contratualizados com a ULS. Tamanho de lista e IDE, com incentivos financeiros associados.	Incentivos para atividades assistenciais específicas e não assistenciais (ensino/investigação, outros). Incentivo para resposta disponibilizada. Modelo de incentivos alinhado com missão abrangente da unidade.
Outras atividades	As incluídas no plano de ação: participação nas equipas dos núcleos de apoio às crianças e jovens em risco e equipa para a prevenção da violência em adultos. Integradas no plano de ação e nos incentivos institucionais: áreas da segurança do utente e centralidade do cidadão – Plano Nacional para a Segurança dos Doentes 2021-2026 Outras realizadas de forma autónoma pelos profissionais. Não integradas ou valorizadas na prática/equipa.	Além das incluídas em plano de ação: integração formal do ensino, investigação e outras atividades na prática clínica da equipa; valorização institucional e contratual destas dimensões. Existência de respostas comuns de maior diferenciação e de referência para USF da região. Oferta complementar centralizada para a população coberta pela ULS (p. ex., cessação tabágica; apoio a lares, telemedicina, etc.)
Investigação	Realizada de forma autónoma e isolada pelos profissionais. Pouco reconhecida ou integrada na prática da equipa.	Incentivo para os profissionais envolvidos na formação e na investigação; tempo protegido e recursos adequados. Integração em rede (PBRN).
Ensino pré-graduado	Eventual, não sistemático; dependente da motivação individual.	Articulação formal com instituições de ensino. Percursos de ensino definidos.
Ensino pós-graduado	Percurso formativo médico existente, integrado com formação de internos. Outros percursos de forma variável.	Mecanismos que incentivem a colaboração e articulação entre as instituições de ensino e a unidade.
Profissionais	Inclui 3 profissões de saúde. Funções clínicas predominantes.	Equipa multiprofissional diversa de acordo com as necessidades particulares da população e/ou integração em percursos formativos ou de investigação. Incluir rede de apoio em nutrição, psicologia, medicina dentária, outros.
Governança	Coordenador médico com funções de representação. Conselho geral é o órgão máximo, que inclui todos os profissionais. Conselho técnico apoia na formação e outras atividades. Instrumentos estratégicos e plano de ação votados por todos os membros.	Coordenador médico que lidera conselho executivo multiprofissional, com representantes dos vários grupos profissionais. Representação assistencial e académica; estrutura adaptada à missão tripartida (cuidados, ensino, investigação); governança participada e orientada para a integração e melhoria contínua dos cuidados e serviços prestados.

CONCLUSÃO

A criação de centros de saúde de base universitária é uma oportunidade e um desafio. Exige a articulação entre estruturas e profissionais e a adaptação à realidade dos CSP das infraestruturas de apoio das ULS para coordenar a formação pré e pós-graduada em CSP, promover o desenvolvimento de redes de investigação e de redes comunitárias para a integração de cuidados.

A criação de centros de saúde de base universitária, com estatuto especial – capaz de encontrar respostas inovadoras para as necessidades não atendidas das populações, que potenciem a prestação de cuidados centrados na pessoa e baseados no valor – tem o potencial de revolucionar os cuidados, promovendo a retenção, satisfação dos profissionais e a melhoria da qualidade dos cuidados.

ACKNOWLEDGMENTS

Os autores declaram não ter utilizado ferramentas de inteligência artificial na elaboração do artigo.

CONTRIBUTO DOS AUTORES

AP, CB, CO, FP, IR, JPA, LM, MDO, NJ, PBG, PaS, PeS, RRM, RC, TM: Desenho e escrita do manuscrito; revisão crítica e validação da versão final.

GC, LMS: Conceção, desenho e escrita do manuscrito; revisão crítica e validação da versão final.

Todos os autores aprovaram a versão final a ser publicada.

REFERÊNCIAS

1. Araújo F. Comunicado - Direção Executiva do Serviço Nacional de Saúde. Serviço Nacional de Saúde. 2024. [consultado 2025 abr 16]. Disponível em: https://www.sns.min-saude.pt/wp-content/uploads/2024/04/Direcao-Executiva-do-Servico-Nacional-de-Saude_comunicado_230424.pdf.
2. Goiana-da-Silva F, Sá J, Cabral M, Guedes R, Vasconcelos R, Sarmiento J, et al. The Portuguese NHS 2024 reform: transformation through vertical integration. *Front Public Health*. 2024;12:1389057.
3. Direção Executiva do Serviço Nacional de Saúde IP. Relatório - Direção Executiva do Serviço Nacional de Saúde, I. P. 2024. [consultado 2025 abr 16]. Disponível em: https://www.sns.min-saude.pt/wp-content/uploads/2024/05/Relatorio_Direcao-Executiva-do-Servico-Nacional-de-Saude-IP.pdf.
4. Nunes A. Vertical integration in healthcare and patient satisfaction: an exploratory analysis of portuguese reforms. *Sustainability*. 2024;16:1078.
5. Beça DC, Pereira AL, Azevedo M, Antunes JP. Evolução dos cuidados de saúde primários em Portugal: lições aprendidas e perspetivas futuras. *Rev Port Med Geral Fam*. 2024;40:524-30.
6. da Luz Pereira A, Chaves Beça D, Antunes JP, Azevedo M, Macedo R, da Costa I, et al. AVALIA-ULS: análise das vantagens e limitações das unidades locais de saúde – perspetivas da medicina geral e familiar – parte I – SPGSAUDE. *Rev Port Gestão Saúde*. 2024;37:18-22.
7. Lopes H, Carlos JS, Rodrigues M, Mestre R, Santana R, Matias T, et al. Relatório do grupo de trabalho criado para a definição de proposta de metodologia de integração dos níveis de cuidados de saúde para Portugal Continental. 2014. [consultado 2025 set 03]. Disponível em: <https://www.sns.gov.pt/wp-content/uploads/2016/05/Relatorio-do-Grupo-de-Trabalho-criado-para-a-definicao-de-proposta-de-metodologia-de-integracao-dos-niveis-de-cuidados-de-saude.pdf>.
8. World Health Organization. The world health report: health systems financing: the path to universal coverage. 2010. [consultado 2024 dez 27]. Disponível em: <https://iris.who.int/handle/10665/44371>.
9. Biscaia AR, Heleno LC. A reforma dos cuidados de saúde primários em Portugal: portuguesa, moderna e inovadora. *Cien Saude Colet*. 2017;22:701-12.
10. Serviço Nacional de Saúde. Relatório da comissão técnica independente para o estudo das ULS Universitárias. 2024. [consultado 2025 mar 20]. Disponível em: <https://www.sns.gov.pt/relatorio-da-comissao-tecnica-independente-para-o-estudo-das-uls-universitarias/>.
11. Associação Portuguesa de Medicina Geral e Familiar. ULS de cariz universitário - posição da APMGF. 2024. [consultado 2025 abr 16]. Disponível em: <https://www.sns.gov.pt/wp-content/uploads/2025/02/CTI-ULS-Relatorio-Final-30-Jan-2025.pdf>.
12. Srivastava D, Mueller M, Hewlett E. OECD health policy studies better ways to pay for health care. 2016 [consultado 2024 dez 23]. Disponível em: <http://dx.doi.org/10.1787/9789264258211-en>.
13. Goodson JD, Bierman AS, Fein O, Rask K, Rich EC, Selker HP. The future of capitation: the physician role in managing change in practice. *J Gen Intern Med*. 2001;16:250.
14. Associação Portuguesa de Medicina Geral e Familiar. Um novo futuro para a medicina geral e familiar. 2023. [consultado 2025 abr 16]. Disponível em: <https://apmgf.pt/wp-content/uploads/2023/05/Um-Novo-Futuro.pdf>.
15. Portugal. Decreto-Lei n.º 103/2023. Diário da República, I Série, n.º 215 (2023/11/07). p. 21-48.
16. Portugal. Decreto-Lei n.º 118/2023. Diário da República, I Série, n.º 244 (2025/12/20). p. 58-73.
17. Kutzin J. Health financing for universal coverage and health system

CONFLITOS DE INTERESSE

ALP é o vice-presidente da Associação Portuguesa de Medicina Geral e Familiar.

GC é o tesoureiro da Associação Portuguesa de Medicina Geral e Familiar.

LMS recebeu apoio da Associação Portuguesa de Medicina Geral e Familiar para a participação no Encontro Nacional de Medicina Geral e Familiar.

PaS recebeu honorários de consultoria de MSD, Boehringer Ingelheim, Astrazeneca; recebeu pagamentos ou honorários por palestras, apresentações, redação de manuscritos ou eventos educacionais de GSK, KRKA, Grunhenthal, Medinfar; recebeu pagamentos de MSD, Boehringer Ingelheim, Astrazeneca para testemunhos de especialista; recebeu apoio para a participação em reuniões e/ou viagens de Grunhenthal, GSK, AstraZeneca.

RM é membro da Comissão de Ética da USISM; é a diretora do Internato Médico de MGF da Ilha de São Miguel.

Os restantes autores declaram não ter conflitos de interesse relacionados com o presente trabalho.

FONTES DE FINANCIAMENTO

Este trabalho não recebeu qualquer tipo de suporte financeiro de nenhuma entidade no domínio público ou privado.

performance: concepts and implications for policy. Bull World Health Organ. 2013;91:602-11.

18. Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. Milbank Q. 2005;83:457-502.
19. Katz G. Implementing value-based health care in Europe: handbook for pioneers. 2020. [consultado 2023 jan 18]. Disponível em: https://eithealth.eu/wp-content/uploads/2020/05/Implementing-Value-Based-Healthcare-In-Europe_web-4.pdf.
20. World Health Organization. Primary care. [consultado 2024 abr 25]. Disponível em: <https://www.who.int/teams/integrated-health-services/clinical-services-and-systems/primary-care>.
21. Starfield B. Is primary care essential? Lancet. 1994;344:1129-33.
22. Barros PP. Cream-skimming, incentives for efficiency and payment system. J Health Econ. 2003;22:419-43.
23. Rice N, Smith P. Approaches to capitation and risk adjustment in health care: an international survey. York: Centre for Health Economics, University of York; 1999.
24. Cortez I. A reforma dos cuidados de saúde primários em 2005: um problema de saúde pública. Rev Port Med Geral Fam.;40:188-91.
25. Correia G, Jacinto N, Reis A, Pereira A, Broeiro-Gonçalves P, Simões S, et al. A new future for family medicine/general practice in Portugal. Rev Port Clínica Geral. 2024;40:408-17.
26. Monteiro BR, Pisco LA. A contratualização com os cuidados de saúde primários na Administração Regional de Saúde de Lisboa e Vale do Tejo, até 2023. Cien Saude Colet. 2024;29:e03142024.
27. Portugal. Decreto-Lei n.º 298/2007. Diário da República, I Série, n.º 161 (2007/08/22). p. 5587-96.
28. Gil Conde M, Correia G, Ramos R, Santiago LM. Processos de apreciação ética como barreira à investigação nos cuidados de saúde primários: reflexão sobre a submissão de um estudo multicêntrico. Acta Med Port. 2024;37:415-8.
29. Conde MG, Rodrigues VL, Ramos RC, Rente A, Broeiro-Gonçalves P, Ribeiro C, et al. Barriers to research in family medicine - interviews with Portuguese family physician researchers. Fam Pract. 2024;41:168-74.
30. Agência de Investigação Clínica e Inovação Biomédica. Documento de apoio à constituição de practice-based research networks (PBRNs) em cuidados de saúde primários (CSP) em Portugal. 2024. [consultado 2025 abr 19]. Disponível em: <https://aicib.pt/2024/03/15/documento-de-apoio-a-constituicao-de-practice-based-research-networks-pbrns-em-cuidados-de-saude-primarios-csp-em-portugal/>.

An Implementation Roadmap to Accelerate Academic Clinical Cancer Research in Portugal: A Multistakeholder Perspective

Um Roteiro para Acelerar a Investigação Clínica Académica em Oncologia em Portugal: Uma Perspectiva Multistakeholder

Ana Sofia V. CARVALHO ¹, Fábio CARDOSO BORGES ², Maria-João CARDOSO ^{3,4}, Júlio OLIVEIRA ⁵, José PAIS SILVA ², Sónia CARVALHO⁶, Luís COSTA ^{4,7,8}, Isabel FERNANDES ^{9,10}, Dora GOMES ^{5,11}, Mónica GOMES ¹², Tamara MILAGRE¹³, Sónia REGO¹⁴, Marta SOARES ^{5,15}, Carlos SOTTOMAYOR ^{14,16,17}, Ana JOAQUIM ², Nuno SOUSA ⁶, José Luís PASSOS COELHO ^{18,19}

Acta Med Port 2026 Jan;39(1):8-13 ▪ <https://doi.org/10.20344/amp.23479>

Keywords: Academic Medical Centers; Biomedical Research; Clinical Trials as Topic; Health Policy; Medical Oncology; Neoplasms; Portugal; Research Personnel

Palavras-chave: Centros Clínicos Académicos; Ensaio Clínicos; Investigação Biomédica; Investigadores; Neoplasias; Oncologia Médica; Política de Saúde; Portugal

INTRODUCTION

Cancer care has progressed remarkably in recent years with the approval of innovative therapies, primarily developed through industry-led clinical trials to support regulatory decisions. While these advancements have significantly improved treatment standards, newly approved medicines often have evidence gaps, particularly regarding real-world effectiveness, optimal treatment sequences, treatment combinations, and de-escalation strategies.¹ Additionally, the rising incidence and prevalence of cancer, along with the substantial cost of new treatments, challenge the financial sustainability of healthcare systems.²

Academic clinical research in oncology constitutes a fundamental link between scientific discovery and clinical practice, addressing knowledge gaps by prioritizing clinically and patient-relevant questions. It fosters the generation of actionable evidence to inform practice, potentially improving resource allocation and benefiting patients. Achieving a balanced integration of commercial and non-commercial

research is essential for advancing cancer care.¹

Despite increasing recognition of investigator-led studies, academic research in Portugal has experienced limited growth. Over the past decade, academic trials have consistently accounted for less than 10% of all approved clinical trials,³ compared to 20% - 45% in other European Union member states.⁴ As oncology comprises approximately one-third of all approved trials annually in Portugal,³ there is a significant opportunity to strengthen academic research in this field, potentially leading to high-impact clinical, economic, and societal gains.

The existing literature has identified several barriers to academic research in Portugal, including limited financial investment, inadequate technical support, and insufficient protected time for research.^{5,6} Nevertheless, there is still no systematic identification of barriers and facilitators specific to oncology, particularly in research on solid tumors. This gap highlights the need for a collaborative, multistakeholder

1. Public and Occupational Health. Amsterdam UMC, location University of Amsterdam. Amsterdam. The Netherlands.

2. European Organisation for Research and Treatment of Cancer (EORTC). Brussels. Belgium.

3. Breast Unit. Champalimaud Foundation. Lisbon. Portugal.

4. Faculty of Medicine. Universidade de Lisboa. Lisbon. Portugal.

5. Portuguese Oncology Institute of Porto (IPO-PORTO). Porto. Portugal.

6. Agency for Clinical Research and Biomedical Innovation (AICIB). Porto. Portugal.

7. Clinical Research Centre. Unidade Local de Saúde Santa Maria. Lisbon. Portugal.

8. Unidade Local de Saúde Santa Maria. Lisbon. Portugal.

9. National Program for Oncological Diseases. Directorate-General of Health. Lisbon. Portugal.

10. EpiDoC Unit. Nova Medical School. Universidade NOVA de Lisboa. Lisbon. Portugal.

11. Radiation Oncology Speciality College. Portuguese Medical Association. Lisbon. Portugal.

12. North Branch. Portuguese Cancer League. Lisbon. Portugal.

13. EVITA. Lisbon. Portugal.

14. EuropaColon Portugal. Porto. Portugal.

15. Portuguese Association for Cancer Research. Porto. Portugal.

16. Medical Oncology Speciality College. Portuguese Medical Association. Lisbon. Portugal.

17. Unidade Local de Saúde Matosinhos. Matosinhos. Portugal.

18. Portuguese Society of Oncology. Coimbra. Portugal.

19. Hospital da Luz Lisboa. Lisbon. Portugal.

 **Autor correspondente:** Fábio Cardoso Borges. fabio.borges@eortc.org

Revisão por/Reviewed by: Gabriela Fernandes , Pedro Silvestre Madeira .

Recebido/Received: 03/06/2025 - **Aceite/Accepted:** 24/10/2025 - **Publicado/Published:** 02/01/2026

Copyright © Ordem dos Médicos 2026



approach and a comprehensive roadmap that targets clinical, organizational, and policy levels to accelerate academic cancer research in Portugal. Implementation science, which bridges the gap between knowledge and practice, may be instrumental in systematically mapping challenges and guiding structured actions to foster progress.⁷

At the 2024 National Congress of the Portuguese Society of Oncology, a multistakeholder session was convened with two main objectives: 1) to systematically identify barriers and facilitators to advancing academic clinical cancer research in Portugal, from a multilevel and multisectoral perspective, 2) to propose strategies, while fostering national collaboration. An iterative, implementation science-based approach was employed to develop a roadmap [Fig.1 and Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/23479/15855>)]. This article presents the outcomes of this collaborative initiative, outlining concrete actions for relevant national actors.

Section 1: Barriers and facilitators to advance academic clinical cancer research in Portugal

Barriers and facilitators were categorized following the constructs of the 'Tailored Implementation for Chronic Diseases' (TICD) checklist,⁸ which comprises social, political, and legal factors; organizational change capacity; incentives and resources; professional interactions; pa-

tient factors; practice/clinical trials factors; and individual health professional factors (Appendix 2: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/23479/15856>).

Among social, political, and legal factors, key barriers identified included the insufficient prioritization of academic trials, the lack of funding opportunities, and lengthy assessment timelines from national regulatory agencies. In contrast, the existence of a national healthcare system with broad population coverage was seen as a major enabler.

Regarding incentives and resources, the lack of dedicated research time and insufficient technical support were perceived as the main barriers. Concerning professional interactions, limited engagement within the Portuguese network and with international counterparts was considered a significant barrier.

At the patient level, limited engagement and restricted access to information were perceived as key barriers. At the health professional level, a major barrier was the lack of recognition of the value of academic research, insufficient recognition of scientific achievements (such as publications), and insufficient experience and guidance. As key enablers, training and guidance by regulatory agencies were highlighted. At practice/clinical trial level, narrow eligibility criteria and the requirement for large sample sizes were emphasized as relevant barriers.

1. Selection of national oncology multi-profile stakeholders

Jun. - Aug. 2024

- Stakeholders included representation of the promotor, medical oncologists, surgical oncologists, hospital manager, national society of oncology and academic organization.

2. Literature review

Sep. - Oct. 2024

- Scientific papers and grey literature (national reports, institutional websites and others) were identified and analysed by the leading author (ASVC) to identify barriers and enablers to advance academic clinical research in the Portuguese context.

3. Survey to stakeholders from phase 1

Oct. 2024

- The stakeholders replied to two open-questions via email to the first authors: "from your perspective, please identify 1) two/three challenges that present as barriers to carrying out clinical research initiated by the researcher in Portugal; 2) two/three opportunities, which you consider as potential facilitators of change."

4. Online focus group with stakeholders from phase 1

Oct. 2024

- Online focus group (90 minutes) with all stakeholders identified in phase 1.
- Structure of the focus group: 1) summary of barriers and enablers from the literature and identified by the stakeholders, presented by the leading author (ASVC) following the Tailored Implementation for Chronic Diseases (TICD) checklist; 2) group discussion.

5. Public panel discussion in a national oncology conference

Nov. 2024

- Structure of the session: 1) the surgical oncologist (MJC) and promotor (AJ) presented their perspective; 2) the leading author (ASVC) presented the barriers, enablers and proposed implementation strategies; 3) panel discussion with the speakers, one oncologist/head of medical society, one oncologist/hospital manager and representatives of regulator and scientific societies.

6. Targeted additional stakeholders consultation

Jan. - Apr. 2025

- Stakeholders were invited individually to contribute to this perspective via phone and/or email, including patient organizations, medical oncologist researchers and cancer research organizations. Input was received via email and incorporated in the perspective.

Figure 1 – Phases of the collaborative development of an implementation roadmap to accelerate academic clinical cancer research in Portugal

Section 2: A collaboratively developed implementation roadmap

Drawing on the barriers and enablers identified, the multistakeholder group developed a roadmap towards imple-

mentation (Table 1). Stakeholders responsible for action were categorized according to the three health system levels – policy, organizational and clinical –, thus answering the question “who should do what?”.

Table 1 – Proposed implementation strategies by key actors at the Portuguese cancer care ecosystem (part 1 of 2)

Governmental bodies: Ministries of Health, Finances, Economy, Science, Education and Innovation	
Political commitment and leadership	- Secure multisectoral governmental commitment to prioritise and fund structured cancer clinical research, recognising its short-, medium-, and long-term economic benefits, e.g. leveraging the recently created National Innovation Agency (“Agência Nacional da Inovação”), considering the development of targeted national strategies to foster academic clinical research in the cancer field. - Integrate cancer clinical research as a core component of oncology practice, with national-level investment to embed clinical trials into routine care. - Promote legislation to encourage private donations to research through fiscal incentives and tax benefits.
Legislation	- Promote the creation of clinical trial support units in reference centres to assist researchers from trial planning to completion, including grant application support. - Enhance career attractiveness and stability for professionals in research through fair financial compensation and growth opportunities to support long-term retention. - Promote the recruitment of clinician-scientists with dedicated time for cancer research. - Promote the concentration of research expertise in selected centres, ensuring patient access through integrated cancer care and research networks. - Ensure the streamlined and consistent application of current and future legislation and regulations, preventing unnecessary bureaucratic burden.
Funding	- Invest in national and international funding for cancer clinical trials focusing on patient-centred research and pragmatic designs, through the appropriate funding agencies for this domain and fostering the generation of high-quality real-world data. - Invest in cancer clinical research by providing dedicated funding to clinical research centres, ensuring financial autonomy for research units separate from direct care delivery. - Establish mechanisms to provide organizations with technical research support. - Foster collaboration between governmental bodies and private sector to leverage funding, resources, and expertise for cancer clinical research initiatives.
Advisory, regulatory and funding agencies with a role in research	
Prioritise necessary changes, communication, and influence	- Promote funding opportunities for cancer clinical research. - Develop strategic partnerships with foundations, academic institutions, and non-governmental organizations to increase funding for academic cancer research. - Invest in national funding to improve compensation for research sites and patients. - Ensure the streamlined and consistent application of regulations, while preventing unnecessary bureaucratic burden. - Develop and monitor indicators related to the number of academic-led clinical trials. - Encourage and guide organizations in monitoring the percentage of cancer patients with access to clinical trials at national, regional, and local levels.
Domain knowledge, awareness, skills	- Encourage the integration of clinical trials into standard cancer care by raising awareness and developing dedicated cancer guidelines. - Promote the simplification of bureaucratic processes to enhance the efficiency of clinical trial assessments. - Develop standardised submission documents, such as protocol and informed consent templates, to streamline preparatory steps and assessment. - Support organizations in building technical cancer research teams and providing logistical support for large projects, including consortia and public-private partnerships. - Establish mechanisms to ensure researchers have seamless access to information and the opportunity to clarify inquiries regarding clinical trial development.
Portuguese Medical Association and Medical Colleges of cancer-related specialties	
Training, regulation and support	- Encourage the training of medical oncologists and cancer-related specialists in clinical research by ensuring that dedicated research training periods are preserved and monitored. - Consider establishing protocols with national and international organizations with capacity to offer research training and internships.

Table 1 – Proposed implementation strategies by key actors at the Portuguese cancer care ecosystem (part 2 of 2)

Medical and scientific societies related to cancer, including the Portuguese Society of Oncology	
Awareness and skills of professionals and availability of resources	- Ensure the regular update of a web platform centralising all cancer clinical trials in Portugal, notably the recently launched platform 'Portugal Clinical Studies'. - Raise awareness among cancer-related healthcare professionals about the importance of regularly consulting available platforms to determine if their patients are eligible to participate in clinical trials. - Develop training programs focused on clinical cancer research. - Contribute to the establishment of national networks for cancer-related healthcare professionals, potentially linked with international networks, to foster collaboration and research.
Hospital Management Boards, Clinical Directors and Heads of Oncology Departments	
Attitudes, awareness and skills of health professionals	- Develop and support initiatives to enhance awareness of the potential of academic research, notably highlighting the importance of embedding clinical trials into standard cancer care, instead of considering them as a last resource for patients. Initiatives should also include training programs and forums for discussion between clinicians and translational researchers. - Invest in well-resourced clinical trial support units, prioritising expertise in cancer clinical research, to provide targeted guidance and assistance with funding acquisition. - Acknowledge and promote the value of participating in international cancer research networks.
Communication, influence and referral processes	- Prioritise academic cancer research, by ensuring expedited contract resolution and facilitating financial approval of in-clinical trial standard of care procedures. - Establish partnerships with universities capable of supporting research activities, including statistical advice, project initiation, and management. - Establish and develop intra- and inter-organisational networks. - Develop strategic partnerships with foundations and academic institutions to enhance funding availability for academic cancer research. - Establish patient advisory boards to better identify unmet needs. - Monitor the proportion of cancer patients, by cancer type, with access to clinical trials throughout their care pathway, and benchmark with other cancer centres and registries.
Patients and patient representatives	
Patient needs, beliefs and knowledge	- Collaborate with clinical trials support units to ensure patient involvement from the outset of projects. - Contribute to setting research priorities by identifying unmet patient needs and patient-relevant outcomes. - Contribute to study design, synopses, informed consent, and patient information documentation. - Participate in trial steering committees to provide patient perspectives on trial conduct. - Invest in dissemination strategies and educational materials to raise awareness and literacy on clinical trials among the general population and cancer patients.
Healthcare professionals involved in cancer care	
Attitudes, awareness and skills	- Acknowledge the value of academic cancer research. - Develop and support initiatives to enhance knowledge and awareness, such as training sessions. - Develop educational materials for the population, in collaboration with patients. - Contribute to enhancing cancer patients' health literacy regarding clinical trial participation.
Communication and influence	- Contribute to the establishment of national collaborative networks for cancer patient referrals. - Actively engage in international collaborative networks. - Create coalitions of multi-level cancer stakeholders to discuss and formulate long-term proposals for increasing knowledge and awareness. - Persuade decision-makers to prioritise cancer clinical research, highlighting its role in advancing standard care, prioritising patient well-being, and implementing cost-effective interventions.

At the policy level, multisectoral prioritization and investment in academic cancer research are critical to strengthening both short- and long-term resilience in cancer care, improving patient outcomes, and ensuring the sustainability of the healthcare system. Notably, academic research should be recognized and regulated as part of standard clinical cancer practice, supported by well-resourced "clinical trial support units" with expertise in trial design and biostatistics,

potentially centralized and connected through coordinated cancer care and research networks. Advisory, regulatory, and funding agencies play a vital role in raising awareness, providing resources, and supporting healthcare professionals in operationalizing academic cancer trials.

At the organizational level, hospital managers, clinical directors and cancer unit heads should strengthen engagement in intra- and inter-organizational networks, as well

as in international collaborative counterparts. Another key strategy is the development and sustained implementation of initiatives to enhance professionals' knowledge and awareness. In addition, a more proactive and efficient approach to trial set-up at the organizational level, along with sound resource allocation decisions, should be actively encouraged.

At the clinical level, patient involvement, either through advocates or organizations, should be strengthened. Patient representatives should be highly engaged in all research stages to raise awareness, promote interest and participation, and ensure patient-centered cancer research. Health professionals involved in cancer care should value academic research as a tool to improve care and outcomes, while contributing to peer and patient education efforts.

CONCLUSION

The optimal use of newly emerged cancer treatments is often poorly documented, leaving clinically relevant questions unanswered. This challenges the financial sustainability of healthcare systems and hinders progress towards more patient-centered cancer care. These questions are often not of commercial interest, thus unlikely to be answered by the commercial sector. In this context, it is incumbent on society to develop solutions to optimize cancer management and treatment. This article includes the perspectives of patient representatives, clinicians, hospital managers, medical and scientific societies, and public health specialists, using an implementation science lens. We showcase the challenges to overcome, the facilitators to leverage, and propose a roadmap to accelerate academic cancer research in Portugal. While we aimed to be inclusive, we were unable to gather input from all relevant stakeholders. Given the critical importance of collaboration, it is imperative to continue strengthening awareness among national stakeholders involved in cancer care regulation and delivery.

We conclude that independent clinical cancer research must be prioritized at policy, organizational and clinical levels in Portugal, to bridge the evidence-gap in pre- and post-approval settings focused on patient needs. This should be underpinned by increased, consistent and predictable public financial investment to ensure embedding of clinical trials into routine cancer care, stronger national and international multistakeholder collaboration, enhanced patient involvement, and greater training and technical support for healthcare professionals. Despite initial investment, patient-centered research may prove cost-saving in the medium to long term. Good practices from other European countries could serve as inspiration for these efforts,⁹ adapted to the national context. Furthermore, efforts to increase patients' and society's health literacy regarding cancer clinical trials are crucial. Portuguese cancer-related patient organiza-

tions are willing to be more frequently engaged in various steps of research and development efforts and are also particularly motivated to ensure that cancer research is better aligned with patients' needs.¹⁰

Improving public investment, awareness among healthcare professionals and patients, collaboration with patient organizations, and access to cancer clinical trials are critical levers to enhance the competitiveness of the Portuguese national health system. While not emphasized in the stakeholder discussions, factors such as improvements in health data infrastructure for secondary use and the strategic use of artificial intelligence tools have the potential to drive innovation in clinical trials and enhance overall health system performance. Recent initiatives, such as the integration of artificial intelligence in the recently launched "Portugal Clinical Studies" platform represent promising steps in this direction. These combined efforts may yield measurable health and economic benefits for the Portuguese society.

PREVIOUS AWARDS AND PRESENTATIONS

This work has not been fully presented or published elsewhere. Portions of its content were shared at the 2024 Portuguese Society of Oncology's Congress (session: "Clinical research in Portugal: challenges and opportunities"), providing a foundation for multistakeholder input that shaped this final manuscript.

ACKNOWLEDGMENTS

The authors gratefully acknowledge the Board and staff of the Portuguese Society of Oncology for their dedicated support to this initiative.

The authors have declared that no AI tools were used during the preparation of this work.

AUTHOR CONTRIBUTIONS

ASVC, FCB, JLPC: Conceptualization; visualization; writing – original draft; writing – review & editing.

MJC, JO, SC, LC, IF, DG, MG, TM, SR, MS, CS, NS: Validation; writing – review & editing.

JPS, AJ: Conceptualization; visualization; validation; writing – review & editing.

All authors approved the final version to be published.

CONFLICTS OF INTEREST

ASVC has received travel support from the Portuguese Society of Oncology.

FCB has received a fellowship grant from the European Organisation for Research and Treatment of Cancer (EORTC) Cancer Research Fund; received consulting fees from the National Authority for Medicines and Health Products (INFARMED I.P.).

MJC has received a grant from the European Union's

Horizon Europe research and innovation programme; received honoraria from AstraZeneca, Merck KGaA, and Novartis; serves on the board of Mama Help.

JO serves on the Board of the Organisation of European Cancer Institutes.

JPS has received consulting fees from INFARMED I.P.; received honoraria from the Association of Integrative Medicine (AIM).

IF serves on the Board of the National Program for Oncological Diseases; received consulting fees from INFARMED I.P.

TM has received honoraria from Illumina and is on

boards for the National Cancer Hub Portugal and ePAG ERN GENTURIS.

MS has received honoraria from Roche, AstraZeneca, Eli Lilly, MSD, Pfizer, Pierre Fabre, Janssen, Takeda, Merck KGaA, BMS, Amgen and Daiichi Sankyo; has received travel support from MSD, Pfizer, Roche and AstraZeneca.

NS serves on the boards of the Portuguese Association for Cancer Research (AICIB) and the P5 Clinical Digital Center; is Chief Medical Officer for Pathena; formerly served on the board of 2CA – Centro Clínico Académico de Braga.

All other authors have no conflicts of interest to declare.

REFERENCES

1. Leary A, Besse B, André F. The need for pragmatic, affordable, and practice-changing real-life clinical trials in oncology. *Lancet*. 2024;403:406-8.
2. Organisation for Economic Co-operation and Development. Tackling the impact of cancer on health, the economy and society. Paris: OECD; 2024.
3. Autoridade Nacional do Medicamento e Produtos de Saúde IP. Evolução anual (2005 a 2022) – ensaios clínicos ao abrigo da diretiva 2001/20 de 04 de abril. [cited 2024 Nov 09]. Available from: https://www.infarmed.pt/documents/15786/6307769/2005-4T2022_PT/051e8cdc-56a5-5405-7921-c04a3a7b93ff.
4. Citeline Custom Intelligence. EU Benchmark Clinical Research. 2023. [cited 2025 Mar 20]. Available from: <https://dcrfonline.nl/wp-content/uploads/sites/12/2023/12/EU-Benchmark-Clinical-Research.pdf>.
5. Ferreira JP, Leite-Moreira A, Da Costa-Pereira A, Soares AJ, Robalo-Cordeiro C, Jerónimo C, et al. Investigação clínica da iniciativa do investigador em Portugal: identificação de problemas e propostas para melhoria. *Acta Med Port*. 2023;36:305-8.
6. Borges-Carneiro F, Torre Souto M, Silva I, Leão Moreira P, Ferraz de Oliveira P, Lopes DJ, et al. Clinical trials in Portugal: past and future. position paper from the colleges of clinical pharmacology and pharmaceutical medicine. *Acta Med Port*. 2024;37:585-8.
7. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci*. 2015;10:1-13.
8. Flottorp SA, Oxman AD, Krause J, Musila NR, Wensing M, Godycki-Cwirko M, 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. *Implement Sci*. 2013;8:1-11.
9. Belgian Health Care Knowledge Centre (KCE). 2024 - BeNeFIT4: Fourth BeNeFIT call for comparative effectiveness studies with ZonMw. 2024. [cited 2025 Mar 13]. Available from: <https://kce.fgov.be/en/kce-trials/calls/2024-benefit4-fourth-benefit-call-for-comparative-effectiveness-studies-with-zonmw>.
10. Roquette C, Crisóstomo S, Milagre T, Ribeiro RS, Pedro AR, Valente A. Patient organisations' views, motivations and experiences on patient involvement in cancer research: a pilot study in Portugal. *BMJ Open*. 2024;14:e077444.

Adaptation and Validation of Ethics in Health Care Questionnaire Version 2 (EHCQ-2) to European Portuguese

Adaptação e Validação do Questionário de Ética em Cuidados de Saúde Versão 2 (EHCQ-2) para Português Europeu

Filipa C. MOREIRA ¹, Cecília LEÃO ², João BESSA ^{3,4}, Pedro M. TEIXEIRA ⁴

Acta Med Port 2026 Jan;39(1):14-22 • <https://doi.org/10.20344/amp.23531>

ABSTRACT

Introduction: Even though ethical decision-making is a cornerstone of medical practice there is a lack of validated tools to assess ethical sensitivity among medical students, junior, and senior doctors. The aim of this study was to adapt and validate the Ethics in Health Care Questionnaire – Version 2 (EHCQ-2) for use in Portugal, ensuring its relevance in evaluating ethical sensitivity within the Portuguese healthcare context.

Methods: The EHCQ-2 was translated into European Portuguese and culturally adapted through a rigorous process involving forward and back-translation, expert review, cognitive interviews with medical professionals, and pilot testing. A validation study was conducted with a sample of 156 participants, including medical students, junior, and senior doctors, to evaluate the questionnaire's reliability and validity.

Results: The adapted EHCQ-2 demonstrated good internal consistency (Cronbach's alpha = 0.74) and variable inter-rater reliability (ranging from 0.12 to 0.67 across tasks), reflecting the complexity of ethical dilemmas. Content validity was established through expert evaluation, while construct validity was supported by significant correlations between individual scenarios and overall scores (e.g., $r = 0.683$ for Scenario 7). Regression analysis revealed that sub-scales measuring issue identification, explanation sophistication, and value recognition collectively explained 99.6% of the variance in total scores, underscoring the questionnaire's robust predictive validity.

Conclusion: The European Portuguese version of the EHCQ-2 is a reliable and valid tool for assessing ethical sensitivity among medical students, junior and senior doctors. Its application can enhance ethics training programs, inform curriculum development, and support efforts to improve ethical decision-making skills in future healthcare professionals. Further research should explore its longitudinal utility and applicability in diverse cultural contexts.

Keywords: Decision Making/ethics; Education, Medical, Undergraduate/ethics; Ethics, Medical; Portugal; Reproducibility of Results; Surveys and Questionnaires; Translating

RESUMO

Introdução: Apesar da tomada de decisão ética ser um pilar fundamental da prática médica persiste uma carência de instrumentos validados para avaliar a sensibilidade ética entre estudantes de medicina, médicos internos e médicos especialistas. Este estudo teve como objetivo adaptar e validar o Questionário de Ética em Cuidados de Saúde – Versão 2 (EHCQ-2) para uso em Portugal, garantindo a sua relevância na avaliação da sensibilidade ética no contexto do sistema de saúde português.

Métodos: O EHCQ-2 foi traduzido para o português e adaptado culturalmente por meio de um rigoroso processo que envolveu tradução e retroversão da tradução, revisão por especialistas, entrevistas cognitivas com profissionais médicos e testes piloto. Um estudo de validação foi conduzido com uma amostra de 156 participantes, incluindo estudantes de medicina, médicos internos e médicos especialistas, para avaliar a confiabilidade e a validade do questionário.

Resultados: O EHCQ-2 adaptado demonstrou boa consistência interna (alfa de Cronbach = 0,74) e confiabilidade interavaliadores variável (variando de 0,12 a 0,67 entre tarefas), refletindo a complexidade dos dilemas éticos. A validade de conteúdo foi estabelecida por meio da avaliação de especialistas, enquanto a validade de construção foi corroborada por correlações significativas entre os cenários individuais e as pontuações gerais (por exemplo, $r = 0,683$ para o Cenário 7). A análise de regressão revelou que as subescalas que medem a identificação do problema, a sofisticação da explicação e o reconhecimento de valores explicaram coletivamente 99,6% da variância nas pontuações totais, reforçando a robusta validade preditiva do questionário.

Conclusão: A versão portuguesa do EHCQ-2 é uma ferramenta confiável e válida para avaliar a sensibilidade ética entre estudantes de medicina, médicos internos e especialistas. A sua aplicação pode aprimorar programas de educação ética, contribuir para o desenvolvimento curricular e apoiar esforços para aprimorar as habilidades de tomada de decisão ética em futuros profissionais de saúde. Será essencial no futuro explorar a sua utilidade longitudinal e aplicabilidade em diversos contextos culturais.

Palavras-chave: Educação de Graduação em Medicina/ética; Ética Médica; Inquéritos e Questionários; Portugal; Reprodutibilidade dos Resultados; Tomada de Decisão/ética; Tradução

1. Department of Otorhinolaryngology and Head and Neck Surgery. Hospital de Braga. Braga. Portugal.

2. Life and Health Sciences Research Institute (ICVS). School of Medicine. Universidade do Minho. Braga. Portugal.

3. Department of Psychiatry. Hospital de Braga. Braga. Portugal.

4. Population Health. Life and Health Sciences Research Institute (ICVS). School of Medicine. Universidade do Minho. Braga. Portugal.

✉ **Autor correspondente:** Filipa C. Moreira. cmoreira.filipa@gmail.com

Recebido/Received: 03/07/2025 - **Aceite/Accepted:** 07/10/2025 - **Publicado Online/Published Online:** 26/11/2025 - **Publicado/Published:** 02/01/2026

Copyright © Ordem dos Médicos 2026



KEY MESSAGES

- Even though ethical decision-making is a cornerstone of medical practice, there is a lack of validated tools to assess ethical sensitivity.
- The adapted EHCQ-2 provides a reliable and valid tool, for both research and practice.
- This formative measurement model captures the multidimensional nature of ethical reasoning.
- This questionnaire could enhance ethics training programs, curriculum development, and ethical decision-making skills.

INTRODUCTION

Medical ethics has undergone significant transformations over the centuries, shaped by social, religious, and technological advancements, as well as evolving organizational models and economic pressures within the healthcare sector.^{1,2} In the near future, medical ethics will increasingly need to address emerging challenges, such as artificial intelligence (e.g., decision algorithms, machine learning, biobanking), genetics (e.g., genetic engineering, reproductive biology, gene therapy), healthcare systems (e.g., resource allocation, funding), and health literacy.^{3,4} Clinicians encounter ethically challenging situations daily, from end-of-life discussions to decisions about limiting care. Ethical decision-making is therefore a foundational competency for medical professionals, requiring the ability to recognize ethical dilemmas, identify relevant values, and make reasoned judgments in complex clinical scenarios.^{5,6}

Recognizing the importance of ethics training, numerous instruments have been developed to assess ethical sensitivity and decision-making among medical students and residents.⁷⁻¹⁰ However, many of these tools lack validation or are tailored to specific cultural contexts, limiting their applicability in diverse settings.^{11,12} This gap highlights the need for culturally adapted instruments that can effectively evaluate ethical reasoning across different populations.¹³

During a systematic review on the effectiveness of medical ethics training,¹⁴ we identified the Ethics in Health Care Questionnaire – Version 2 (EHCQ-2) as a promising tool. The EHCQ-2 stands out due to its scenario-based design, which combines quantitative scoring with qualitative insights into participants' reasoning processes.^{8,10} By presenting realistic ethical dilemmas and asking participants to both select responses and provide written explanations, the EHCQ-2 captures a multidimensional view of ethical sensitivity, including issue identification, sophistication of reasoning, and value recognition. This dual approach makes it particularly well-suited for evaluating the nuanced nature of ethical decision-making in medical practice.

Despite its demonstrated utility in English-speaking contexts, the EHCQ-2 had not been adapted or validated for use in Portugal. Given the importance of cultural relevance in assessing ethical sensitivity, the aim of this study was

to adapt and validate the EHCQ-2 for use among medical students, junior (resident), and senior doctors in Portugal. Specifically, we sought to:

- Translate the EHCQ-2 into Portuguese and culturally adapt it to align with local ethical norms and healthcare practices.
- Assess the reliability of the adapted questionnaire through measures of internal consistency and inter-rater reliability.
- Evaluate the validity of the adapted questionnaire using content validity and construct validity analyses.

By addressing these objectives, this study aims to provide a robust tool for evaluating ethical sensitivity in the Portuguese context, ultimately contributing to improved ethics training and professional development in healthcare.

METHODS

Translation and cultural adaptation

The Ethics in Health Care Questionnaire – Version 2 was translated into European Portuguese through a rigorous, multi-step process to ensure linguistic equivalence and cultural relevance. The process began with forward translation by two independent bilingual translators, followed by reconciliation to produce a single harmonized version. A third bilingual translator then performed back-translation to verify accuracy and identify potential discrepancies. The translated questionnaire was reviewed by a panel of experts in medical ethics and linguistics to ensure that the scenarios and response options were culturally appropriate and aligned with ethical norms in Portugal.

Cognitive interviews were conducted with 15 medical professionals, including medical students, junior, and senior doctors, to assess the clarity, comprehensibility, and cultural relevance of the translated questionnaire. Based on feedback from these interviews, adjustments were made to refine the wording and context of specific items. For example, certain scenarios were rephrased to better reflect local healthcare practices, and culturally specific terms were clarified to ensure universal understanding.

A good cultural adaptation was defined as the absence

of significant difficulties in understanding or responding to the scenarios by at least 80% of participants during cognitive interviews.

Pilot testing

The adapted questionnaire was pilot tested with 20 participants, comprising medical students, junior doctors, and senior doctors. Pilot testing was intended to evaluate the feasibility, acceptability, and clarity of the questionnaire in a real-world setting. Feedback from participants indicated that the questionnaire was generally comprehensible and culturally appropriate. However, some scenarios required further refinement to address ambiguities or align with local ethical norms. Specific adjustments included:

- Clarifying ambiguous phrasing in Scenario 3 ("Patient's Family") to better reflect family dynamics in the Portuguese context.
- Adjusting specific references in Scenario 6 ("Teenager requests abortion") to ensure alignment with Portuguese legal and ethical guidelines.
- Adding contextual details to Scenario 12 ("Flu Vaccine") to improve its applicability to public health practices in Portugal.

These changes ensured that the final version of the questionnaire was both linguistically accurate and culturally relevant, enhancing its suitability for use in the Portuguese healthcare context.

Validation study design

A validation study was conducted to assess the psychometric properties of the adapted EHCQ-2 as a formative measurement model. The study involved a convenience sample of 156 participants, including medical students (68), junior (43), and senior doctors (45), to evaluate the questionnaire's applicability across different stages of medical training and professional practice.

Inclusion criteria:

- Medical students (5th or 6th year) at University of Minho's School of Medicine.
- Residents completing internships at Braga Hospital.
- Attending physicians working at Braga Hospital.

Exclusion criteria:

- Not fluent in Portuguese.

Participants were asked to respond to 12 ethical scenarios included in the EHCQ-2. Each scenario required participants to:

- Identify the correct (consensual) response.
- Identify the ethical issue presented.
- Provide a short explanation of their reasoning.
- Indicate whether they agreed with a proposed course of action.

Responses were scored using a formal coding system

that evaluated four key domains:

- Correct response (0 - 11 points): Participants received one point for each ethical scenario for which the response matched expert consensus as the most appropriate course of action.
- Issue identification (0 - 36 points): Participants received points for correctly identifying the primary ethical issue in each scenario. Full credit was awarded for responses that matched expert consensus or reflected a nuanced understanding of the dilemma.
- Sophistication of explanation (0 - 60 points): Written explanations were scored based on the depth and balance of reasoning. Higher scores were assigned to responses that demonstrated a sophisticated understanding of competing values and ethical principles.
- Value recognition (0 - 48 points): Participants earned points for identifying relevant ethical values (e.g., autonomy, beneficence, non-maleficence) and explaining their relevance to the scenario.

For example, in Scenario 7 ("The baby with Down syndrome"), a participant who identified the ethical issue as "parental decision-making in the context of disability," provided a balanced explanation weighing parental rights against societal norms, and recognized the values of autonomy and justice would receive high scores across all three domains.

Statistical analysis

The statistical analysis included the calculation of Cronbach's alpha to assess internal consistency, Spearman's rank-order correlations to examine construct validity, and analysis of variance (ANOVA) followed by *post-hoc* tests (Tukey) to compare differences between groups. Predictive validity was evaluated through multiple linear regression analysis, where sub-scales measuring issue identification, explanation sophistication, and value recognition were used as independent variables to predict the total score.

Statistical analyses were conducted to evaluate the reliability and validity of the adapted questionnaire. Descriptive statistics were calculated for each sub-scale and the total score, while correlation and regression analyses were used to assess construct validity. Group comparisons were performed to explore differences in ethical sensitivity based on professional experience.

Ethical approval for the study was obtained from Health Ethics Committee of Braga's Hospital, Ethics Committee for Research in Life and Health Sciences of the University of Minho, and all participants provided informed consent before completing the questionnaire. Responses were kept confidential to ensure data integrity.

RESULTS

The validation study involved a sample of 156 participants, comprising medical students, junior, and senior doctors in Portugal. This diverse sample allowed for the examination of the EHCQ-2's applicability across different stages of medical training and practice.

The adapted EHCQ-2 demonstrated good internal consistency, with a Cronbach's alpha of 0.74, indicating reliable measurement of ethical sensitivity. This value meets the generally accepted threshold (0.7) for reliability in social science research, suggesting that the items within the questionnaire consistently measure a cohesive construct.

Inter-rater reliability, which assesses the degree of agreement between different evaluators, varied considerably across different tasks within the questionnaire, with coefficients ranging from 0.12 to 0.67. This variation may reflect the inherent complexity of the ethical dilemmas presented. Scenarios with higher consensus (e.g., values close to 0.67) tend to involve more clear-cut ethical norms or principles, while those with lower consensus (e.g., values close to 0.12) may reflect more subjective or context-dependent dilemmas, open to multiple interpretations.

Content validity was evaluated through an expert review process. Experts in medical ethics and Portuguese language assessed the translated scenarios and response options, ensuring they reflected culturally relevant ethical

standards and considerations specific to the Portuguese healthcare context. The expert review confirmed that the adapted EHCQ-2 aligns with Portuguese legal and ethical guidelines, supporting its relevance and applicability in this setting.

Descriptive statistics

Descriptive statistics were calculated for the Total Score (0 - 155) and its sub-scales: Total Correct Response Score (0 - 11), Total Identification Ability Score (0 - 36), Total Sophistication of Explanation Score (0 - 60), and Total Value Identification Score (0 - 48). These scores were analyzed across three groups: medical students, junior doctors, and senior doctors (Table 1).

The fact that some participants did not identify ethical issues or explain values raises questions about questionnaire comprehension or response motivation. Contextual factors, such as time pressure or fatigue, may have influenced the quality of responses. Future research should explore strategies to mitigate this issue, such as including incentives or improving questionnaire design.

Correlations

The correlation analysis revealed significant positive correlations between individual scenarios and the total sub-scale scores, supporting the expectations of a formative

Table 1 – Descriptive statistics

		n	Mean	Std. deviation	Minimum	Maximum
Total score (0 - 155)	Student	68	52.721	15.775	6	97
	Senior	45	54.244	17.927	5	88
	Junior	43	50.860	17.710	5	92
	Total n	156	52.647	16.894	5	97
Total correct response score (0 - 11)	Student	68	7.441	0.998	5	9
	Senior	45	6.956	0.878	5	9
	Junior	43	7.442	1.278	5	10
	Total n	156	7.301	1.068	5	10
Total identification ability score (0 - 36)	Student	68	13.676	4.586	0	26
	Senior	45	14.444	5.345	0	24
	Junior	43	13.279	5.063	0	24
	Total n	156	13.788	4.934	0	26
Total sophistication of explanation score (0 - 60)	Student	68	18.176	6.859	0	38
	Senior	45	18.889	7.408	0	34
	Junior	43	17.233	7.505	0	35
	Total n	156	18.122	7.181	0	38
Total value identification score (0 - 48)	Student	68	13.426	4.372	0	25
	Senior	45	13.956	5.117	0	25
	Junior	43	12.907	4.970	0	24
	Total n	156	13.436	4.748	0	25

measurement model. Each scenario contributed independently to the overall ethical sensitivity score, as evidenced by strong and statistically significant Spearman's rank-order correlations. For instance, Scenario 1 ("Voluntary withdrawal of treatment") showed a correlation of $r = 0.485$ ($p < 0.001$), while Scenario 3 ("Patient's family") demonstrated an even stronger correlation of $r = 0.613$ ($p < 0.001$). Notably, Scenario 7 ("The baby with Down syndrome") and Scenario 12 ("Flu vaccine") exhibited particularly high correlations, with $r = 0.683$ ($p < 0.001$) and $r = 0.671$ ($p < 0.001$), respectively (Table 2).

These findings suggest that certain scenarios resonate more strongly with participants due to their relevance to real-world clinical practice. For example, scenarios involving family dynamics, such as Scenario 3 ("Patient's family") and Scenario 7 ("The baby with Down syndrome"), likely show stronger correlations because they reflect situations healthcare professionals encounter frequently in their daily practice. Ethical dilemmas involving family decision-making often require navigating competing values, such as patient autonomy and familial concerns, making them especially

significant in both medical education and clinical practice (Table 3). Similarly, public health dilemmas, like those presented in Scenario 12 ("flu vaccine"), may elicit stronger responses due to their societal implications and alignment with contemporary healthcare challenges, such as vaccination hesitancy and resource allocation. These types of scenarios highlight the intersection of individual ethics and broader public health considerations, which are increasingly relevant in modern medical practice (Table 4).

The variability in correlation strengths across scenarios underscores their distinct roles in shaping ethical sensitivity. This pattern aligns with the formative measurement model, where indicators contribute independently to the latent construct. The robust correlations also indicate that the questionnaire is sensitive to differences in how participants engage with specific ethical dilemmas, further supporting its utility as a tool for assessing ethical sensitivity in medical education and practice. These results collectively reinforce the suitability of the EHCQ-2 as a formative measurement model for evaluating ethical reasoning in healthcare professionals.

Table 2 – Identification ability score results

Scenario	Total identification ability score		
S01 Voluntary withdrawal of treatment	Spearman's rho	0.523	***
	p-value	< 0.001	
S02 The Patient with epilepsy	Spearman's rho	0.512	***
	p-value	< 0.001	
S03 Patient's family	Spearman's rho	0.645	***
	p-value	< 0.001	
S04 Patient refuses transfusion	Spearman's rho	0.502	***
	p-value	< 0.001	
S05 Disclosure of HIV positive status	Spearman's rho	0.484	***
	p-value	< 0.001	
S06 Teenager requests abortion	Spearman's rho	0.535	***
	p-value	< 0.001	
S07 The baby with Down syndrome	Spearman's rho	0.566	***
	p-value	< 0.001	
S08 Child with leukemia	Spearman's rho	0.582	***
	p-value	< 0.001	
S09 The attractive patient	Spearman's rho	0.440	***
	p-value	< 0.001	
S10 The resident	Spearman's rho	0.544	***
	p-value	< 0.001	
S11 The new face	Spearman's rho	0.519	***
	p-value	< 0.001	
S12 Flu vaccine	Spearman's rho	0.616	***
	p-value	< 0.001	

*, $p < 0.05$; **, $p < 0.01$; ***, $p < 0.001$

Linear regression

The multiple linear regression analysis provided robust evidence for the predictive validity of the adapted EHCQ-2. The three sub-scales – total identification ability score (TIAS), total sophistication of explanation score (TSES), and total value identification score (TVIS) – collectively explained 99.6% of the variance in the total score ($R^2 = 0.996$, adjusted $R^2 = 0.996$), with a low root mean square error (RMSE = 1.048), indicating high accuracy in predicting overall ethical sensitivity (Table 5).

The ANOVA results confirmed the statistical significance of the model [$F(3, 152) = 13,373.591$, $p < 0.001$]. Standardized coefficients revealed that TSES had the strongest impact ($\beta = 0.454$, $p < 0.001$), followed by TIAS ($\beta = 0.298$, $p < 0.001$) and TVIS ($\beta = 0.259$, $p < 0.001$).

Group comparisons

Analysis of variance (ANOVA) was conducted to compare mean scores across participant groups (medical students, junior, and senior doctors). No statistically significant differences were found for the total score (0 - 155) between

groups [$F(2, 153) = 1.234$, $p = 0.293$], indicating that overall ethical sensitivity does not vary significantly based on professional experience. *Post-hoc* comparisons using Tukey's adjustment revealed minor differences in specific sub-scales. For instance, students scored significantly higher than seniors in the total correct response score [mean difference = 0.486, SE = 0.202, $t(153) = 2.402$, $p = 0.046$], while seniors scored marginally higher than juniors in the total sophistication of explanation score [mean difference = -0.486, SE = 0.224, $t(153) = -2.168$, $p = 0.08$].

While no overall differences were observed, the marginal differences observed in sub-scales, such as the superior performance of students in the total correct response score, may reflect their recent exposure to formal ethics training. In contrast, the greater sophistication in explanations provided by senior doctors (higher scores in the total sophistication of explanation score) may result from accumulated clinical experience, suggesting that practice enhances the depth of ethical reasoning. These observations suggest opportunities for targeted educational interventions. Future research could explore these patterns further for refining ethics

Table 3 – Sophistication of explanation score results

Scenario	Total sophistication of explanation score		
S01 Voluntary withdrawal of treatment	Spearman's rho	0.485	***
	p-value	< 0.001	
S02 The patient with epilepsy	Spearman's rho	0.536	***
	p-value	< 0.001	
S03 Patient's family	Spearman's rho	0.613	***
	p-value	< 0.001	
S04 Patient refuses transfusion	Spearman's rho	0.556	***
	p-value	< 0.001	
S05 Disclosure of HIV positive status	Spearman's rho	0.517	***
	p-value	< 0.001	
S06 Teenager requests abortion	Spearman's rho	0.535	***
	p-value	< 0.001	
S07 The baby with Down syndrome	Spearman's rho	0.521	***
	p-value	< 0.001	
S08 Child with leukemia	Spearman's rho	0.590	***
	p-value	< 0.001	
S09 The attractive patient	Spearman's rho	0.487	***
	p-value	< 0.001	
S10 The resident	Spearman's rho	0.529	***
	p-value	< 0.001	
S11 The new face	Spearman's rho	0.531	***
	p-value	< 0.001	
S12 Flu vaccine	Spearman's rho	0.636	***
	p-value	< 0.001	

*, $p < 0.05$; **, $p < 0.01$; ***, $p < 0.001$

Table 4 – Value identification score results

Scenario	Total value identification score		
S01 Voluntary withdrawal of treatment	Spearman's rho	0.521	***
	p-value	< 0.001	
S02 The patient with epilepsy	Spearman's rho	0.581	***
	p-value	< 0.001	
S03 Patient's family	Spearman's rho	0.598	***
	p-value	< 0.001	
S04 Patient refuses transfusion	Spearman's rho	0.562	***
	p-value	< 0.001	
S05 Disclosure of HIV positive status	Spearman's rho	0.520	***
	p-value	< 0.001	
S06 Teenager requests abortion	Spearman's rho	0.598	***
	p-value	< 0.001	
S07 The baby with Down syndrome	Spearman's rho	0.683	***
	p-value	< 0.001	
S08 Child with leukemia	Spearman's rho	0.607	***
	p-value	< 0.001	
S09 The attractive patient	Spearman's rho	0.535	***
	p-value	< 0.001	
S10 The resident	Spearman's rho	0.566	***
	p-value	< 0.001	
S11 The new face	Spearman's rho	0.551	***
	p-value	< 0.001	
S12 Flu vaccine	Spearman's rho	0.671	***
	p-value	< 0.001	

*: $p < 0.05$; **: $p < 0.01$; ***: $p < 0.001$

Table 5 – Linear regression coefficients

Model		Unstandardized	Standard error	Standardized	t	p
M ₁	(Intercept)	6.843	0.263		26.031	< 0.001
	TIAS	1.020	0.082	0.298	12.484	< 0.001
	TSES	1.069	0.047	0.454	22.909	< 0.001
	TVIS	0.921	0.072	0.259	12.738	< 0.001

curricula and addressing gaps in professional development.

These findings underscore the importance of fostering ethical reasoning as a core competency throughout medical training and practice. The adapted EHCQ-2 provides a reliable and valid tool for assessing these competencies, enabling educators and practitioners to monitor progress and tailor interventions to meet the evolving needs of healthcare professionals.

DISCUSSION

The adaptation and validation of the EHCQ-2 for use in Portugal represents a significant step forward in assess-

ing ethical sensitivity among medical students, junior, and senior doctors. This culturally adapted tool (Appendix 1 : <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/23531/15817>) successfully integrates linguistic nuances and ethical norms specific to the Portuguese healthcare context while retaining the robust psychometric properties of the original questionnaire. The findings demonstrate that the adapted EHCQ-2 effectively captures key dimensions of ethical reasoning, including issue identification, sophistication of explanation, and value recognition, making it a valuable resource for both research and practice.

A notable strength of this study lies in its alignment with the formative measurement model framework. Unlike reflective models, where indicators are expected to correlate highly due to their shared underlying construct, formative models anticipate that indicators contribute independently to the overall construct.^{15,16} The results support this assumption, as the sub-scales – total identification ability score (TIAS), total sophistication of explanation score (TSES), and total value identification score (TVIS) – were found to independently and significantly predict the total score. This finding underscores the importance of retaining all sub-scales to capture the multidimensional nature of ethical sensitivity. For instance, the prominence of TSES as the strongest predictor highlights the critical role of nuanced reasoning in ethical decision-making, while the contributions of TIAS and TVIS reinforce the complexity of ethical reasoning processes.

The correlation analysis further validates the questionnaire's utility. Significant positive correlations between individual scenarios and the total subscale scores indicate that performance on specific tasks meaningfully contributes to overall ethical sensitivity. Scenarios involving family dynamics (e.g., Scenario 3: "Patient's family") and public health dilemmas (e.g., Scenario 12: "Flu vaccine") demonstrated particularly strong correlations, likely reflecting their relevance to real-world clinical practice in Portugal. These findings suggest that certain ethical challenges resonate more strongly with participants due to their frequent occurrence or societal significance, underscoring the questionnaire's ability to capture context-specific ethical reasoning.

Group comparisons showed no statistically significant differences in overall ethical sensitivity among medical students, junior doctors, and senior doctors, although larger studies could detect them. Still, this finding may suggest that ethical reasoning is influenced more by standardized training and exposure to ethical dilemmas than by years of professional experience. However, significant differences in specific sub-scales, such as the total correct response score, where students outperformed seniors, may reflect variations in familiarity with ethical principles or differences in how groups approach ethical challenges. These patterns highlight opportunities for targeted educational interventions, such as reinforcing foundational ethics knowledge among senior doctors or enhancing reasoning sophistication among junior doctors.

The regression analysis provided evidence for the predictive validity of the adapted questionnaire, with the three sub-scales collectively explaining 99.6% of the variance in the total score ($R^2 = 0.996$). This high explanatory power may confirm the questionnaire's ability to capture the key dimensions of ethical sensitivity, further validating its use as a formative measurement tool.

Nevertheless, we also recognize that this high explanatory power may be influenced by the structural proximity between the sub-scales and the total score. This phenomenon may indicate overfitting or multicollinearity, limiting the interpretation of R^2 as robust evidence of predictive validity.

The ANOVA results validate the formative measurement model, as each sub-scale independently and meaningfully contributed to the overall construct of ethical sensitivity.

The strong predictive validity of the sub-scales underscores the questionnaire's ability to measure distinct dimensions of ethical sensitivity. For example, the prominence of TSES as the strongest predictor highlights the critical role of nuanced reasoning in ethical decision-making. Similarly, the contributions of TIAS and TVIS reinforce the multidimensional nature of ethical sensitivity, capturing issue identification, reasoning sophistication, and recognition of ethical values.

The variability observed in inter-rater reliability reflects the inherent complexity of the ethical dilemmas presented. Scenarios with higher consensus tend to involve clear ethical norms or principles, with higher values, while those with lower consensus present lower values, reflecting more subjectivity or context-dependent dilemmas.

Beyond its psychometric properties, the EHCQ-2 has broader implications for medical education and practice. For example, it can be used to evaluate the effectiveness of ethics training programs by assessing changes in ethical sensitivity over time. Longitudinal studies could explore trends in ethical reasoning throughout medical training, identifying critical periods for intervention. Additionally, the questionnaire could serve as a tool for assessing the impact of specific curricular innovations or training modules designed to enhance ethical decision-making skills.

Cultural factors also play a significant role in shaping ethical reasoning within the Portuguese context. The emphasis on family-centered decision-making, collectivism, and respect for authority in Portuguese society may influence how healthcare professionals' approach ethical dilemmas. For instance, scenarios involving family dynamics may elicit stronger responses due to their alignment with cultural norms, highlighting the importance of considering local values when designing ethics training programs. Future research could explore these cultural influences in greater depth, providing insights into how ethical reasoning varies across different cultural contexts.

Despite its strengths, this study has limitations that warrant consideration. First, the sample size, while adequate for initial validation, may not fully represent the diversity of healthcare professionals in Portugal. Expanding the sample to include a broader range of specialties and settings would enhance the generalizability of the findings. Second, the reliance on self-reported responses

introduces the potential for social desirability bias, which may influence participants' answers. Incorporating objective measures, such as simulated ethical scenarios or observational assessments, could mitigate this limitation. Third, while the adapted questionnaire demonstrates strong psychometric properties, its applicability to other Portuguese-speaking countries remains untested. Cross-cultural validation studies are needed to assess its utility in diverse contexts and ensure its relevance beyond Portugal.

The EHCQ-2 presents opportunities for further research and application. Future studies could explore its use in evaluating the impact of ethics training interventions, assessing longitudinal trends in ethical sensitivity, or adapting it for use in other healthcare professions. Additionally, cross-cultural validation studies could expand its applicability to Portuguese-speaking countries and other global contexts, contributing to a deeper understanding of ethical reasoning across diverse populations. As healthcare continues to evolve, tools like the EHCQ-2 will play an essential role in fostering ethical competence and ensuring high-quality patient care.

CONCLUSION

The Portuguese version of the EHCQ-2 demonstrated evidence of reliability and validity for assessing ethical sensitivity among medical students, junior, and senior doctors. Its alignment with a formative measurement model ensures that it captures the multidimensional nature of ethical reasoning, providing actionable insights for educators and practitioners. By addressing gaps in existing assessment tools, this questionnaire has the potential to enhance ethics training programs, inform curriculum development, and may

support efforts to improve ethical decision-making skills in future healthcare professionals.

ACKNOWLEDGMENTS

The authors have declared that no AI tools were used during the preparation of this work.

AUTHOR CONTRIBUTIONS

FM: Data collection and analysis, writing of the manuscript.

CL, JB, PMT: Critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

FUNDING SOURCES

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

REFERENCES

- Schmitz CC, Chow CJ, Rothenberger DA. Colorectal surgeons teaching general surgery residents: current challenges and opportunities. *Clin Colon Rectal Surg.* 2012;25:134-42.
- Hattab AS. Current trends in teaching ethics of healthcare practices. *Dev World Bioeth.* 2004;4:160-72.
- Nandi PL. Ethical aspects of clinical practice. *Arch Surg.* 2000;135:22-5.
- Lehmann LS, Sulmasy LS, Desai S. Hidden curricula, ethics, and professionalism: optimizing clinical learning environments in becoming and being a physician: a position paper of the American college of physicians. *Ann Intern Med.* 2018;168:506-8.
- Daboval T, Moore GP, Ferretti E. How we teach ethics and communication during a Canadian neonatal perinatal medicine residency: an interactive experience. *Med Teach.* 2013;35:194-200.
- Cummings CL. Teaching and assessing ethics in the newborn ICU. *Semin Perinatol.* 2016;40:261-9.
- Sulmasy DP, Geller G, Levine DM, Faden R. Medical house officers' knowledge, attitudes, and confidence regarding medical ethics. *Arch Intern Med.* 1990;150:2509-13.
- Goldie J, Schwartz L, McConnachie A, Jolly B, Morrison J. Can students' reasons for choosing set answers to ethical vignettes be reliably rated? Development and testing of a method. *Med Teach.* 2004;26:713-8.
- Tsai TC, Harasym PH. A medical ethical reasoning model and its contributions to medical education. *Med Educ.* 2010;44:864-73.
- Lohfeld L, Goldie J, Schwartz L, Eva K, Cotton P, Morrison J, et al. Testing the validity of a scenario-based questionnaire to assess the ethical sensitivity of undergraduate medical students. *Med Teach.* 2012;34:635-42.
- Campbell AV, Chin J, Voo TC. How can we know that ethics education produces ethical doctors? *Med Teach.* 2007;29:431-6.
- Daboval T, Ward N, Schoenherr JR, Moore GP, Carew C, Lambrinakos-Raymond A, et al. Testing a communication assessment tool for ethically sensitive scenarios: protocol of a validation study. *JMIR Res Protoc.* 2019;8:e12039.
- González-Blázquez FJ, Ruiz-Hontangas A, López-Mora C. Bioethical knowledge in students and health professionals: a systematic review. *Front Med.* 2024;11:1252386.
- Moreira F, Teixeira P, Leão C. Effectiveness of medical ethics education: a systematic review. *MedEdPublish.* 2021;10:175.
- Bollen KA, Lennox RD. Conventional wisdom on measurement: a structural equation perspective. *Psychol Bull.* 1991;110:305-14.
- Diamantopoulos A, Winklhofer HM. Index construction with formative indicators: an alternative to scale development. *J Mark Res.* 2001;38:269-77.

KEY MESSAGES

- Provides a standardized, detailed instrument specifically designed for evaluating basic suturing competence in medical students.
- Developed through a rigorous process involving multidisciplinary surgical experts and modern psychometric approaches.
- Combines classical test theory and item response theory analyses to ensure robust validity and reliability evidence.
- Aims to identify students who have not yet reached essential competence, supporting safer and more targeted surgical education.

INTRODUCTION

Suturing skills are an essential competence for every young doctor who is expected to be capable of autonomously treating a patient with a regular skin wound. For this reason, this skill must be developed and assessed during undergraduate medical training to ensure that medical students are prepared for this practice immediately after graduation. However, despite most medical educators recognizing this as an essential skill, little is known about how medical schools are assessing suture skills, leading to a problem in acquiring essential competencies. Despite the availability of various formats for assessing technical and surgical competencies in the literature, these tools are targeted towards more complex procedures, mostly applicable to surgery residents and not designed for undergraduates. To the best of our knowledge a suturing skill assessment scale targeted specifically at medical students is lacking. To address this gap, we propose to develop a new scale and obtain validity evidence based on its internal structure.

The proper assessment of competence is a challenging task.¹ This can be caused in part by the struggle to define and isolate the competency to be evaluated, since there are several dimensions for professional competency and even a hierarchy amongst them.^{2,3}

In the past decades, efforts have been made to progress to competency-based curricula, such as the creation of CanMEDS,⁴ Accreditation Council for Graduate Medical Education core competencies,⁵ or Entrustable Professional Activities.⁶ Epstein *et al* explained that competence is contextual, reflecting the relationship between a person's abilities and the tasks they are required to perform in a particular situation in the real world.⁷ Regarding undergraduate performance assessment, students can be assessed in a simulated environment or a real-life one, and, for both, multiple instruments can be used to assess the students, depending on the competence being measured.

Regarding the surgical undergraduate curriculum, surgical skills are unquestionably one of the core components and one of the most relevant abilities expected and required for a medical graduate. Amongst these surgical skills, the ability to perform an acceptable basic suture that can be

autonomously replicated in any scenario should be a requirement for practice. However, recent reports show a concerning trend in the decline of suturing competence among recent medical graduates.⁸

Several suturing assessment scales are available in the literature,⁹ mostly directed to laparoscopic/robotic sutures,¹⁰ microsurgical,¹¹⁻¹³ post-graduate surgical residents,^{12,14-17} or even task-oriented.¹⁸⁻²⁰ Others address basic suturing skills and are targeted at medical students but include the time to perform as one of the components of competence.²¹ The factor of 'time to perform' has been very controversial in the literature since the authors believe the expected competency for the undergraduate should be focused on the quality of the technique, not its speed.

Since competence is contextual and developmental, we consider that the assessment must be tailored to the context. However, when the assessed competence involves a specific technique, most assessment methods are designed with expert-level performance in mind—or at least with expectations of high proficiency—without accounting for varying stages of expertise development.²² This has led us to believe that there is still space to discuss what can be done when the assessment purpose is to discriminate between those who are competent, disregarding the level of expertise, from those who are unable to perform. Additionally, we aim to improve the specificity, detail, and standardization of the assessment tool, reducing subjectivity and making it feasible for less experienced assessors to be used in summative exams, reducing the burden and logistic problems for the faculty and the medical school.

To properly validate and understand the measurement process in educational assessment, complementary approaches from classical test theory (CTT) and item response theory (IRT) provide valuable insights into how well an assessment tool performs.²³ While CTT offers a straightforward way to evaluate test reliability, modern psychometric approaches like the Rasch model analysis, a special case under the umbrella of IRT, can provide more sophisticated information about both the assessment items and student performance.²³

In the context of surgical skills assessment, having precise and reliable measurement tools is crucial, particularly when making high-stakes decisions about student competency. The ability to accurately distinguish between competent and non-competent performance levels requires assessment tools that have undergone rigorous validation.²⁴ This validation should examine not only the basic reliability of the tool but also provide evidence that it measures the intended construct – in this case, basic suturing skills – in a consistent and meaningful way.²⁵ The internal structure of the assessment tool was examined in this study through multiple complementary dimensionality analyses, ensuring that the scale measures a single, coherent construct of basic suturing skills.

This work introduces the Minho Suture Assessment Scale (Minho-SAS), a new evaluation tool using binary (yes/no) items to assess whether undergraduate medical students are competent in basic suturing skills. The primary objective was to provide evidence of validity based on the internal structure of the scale, through both classical test theory and item response theory approaches. Secondary objectives included examining the reliability of the instrument, assessing its dimensionality, and evaluating its feasibility for use in summative and formative assessments within medical education. To our knowledge, this represents the first application of such a thorough psychometric framework to surgical skills assessment.

METHODS

Step 1: Identification of the purpose and domains of the assessment

We intended to create an assessment instrument, in the European Portuguese language, that could identify undergraduates able to perform a correct basic suture. The instrument should be user-friendly and adaptable to the context: summative assessment for 5th-year medical students in a simulated scenario. To the best of our knowledge, no other scale with this purpose and context has been validated.

For guidance on the best practices for scale validation, the work from Boateng *et al* and the standards for educational and psychological testing were used.^{26,27}

The study was approved by the Ethics Committee for Research in Life and Health Sciences (CEICVS) (CEICVS 103/2022).

Step 2: Development of the items of the Minho Suture Assessment Scale

We used both inductive and deductive approaches simultaneously to generate the items. Fourteen skilled surgeons from various backgrounds, such as general surgery, pediatric surgery, gynecology, orthopedics, and urology, were carefully selected to form a focus group. The group employed the Delphi methodology to create a preliminary list of items for the Minho-SAS prototype. Each expert provided initial suggestions and feedback, then refined their views based on group discussions. In the first round, items

Table 1 – Minho Suture Assessment scale translated into the English language

Question	Item	Yes/No	No. of positive assessments
1	Confirms and prepares all necessary materials.	Y/N	242
2	Holds the needle correctly with the needle holder.	Y/N	251
3	Manipulates the needle holder correctly.	Y/N	259
4	Manipulates the tissue forceps correctly.	Y/N	245
5	Places the suture at an appropriate distance from the wound edge and ensures equal distance on both sides.	Y/N	221
6	Demonstrates surgical dexterity in inserting, exteriorizing, and handling the needle at the skin's exit.	Y/N	181
7	Ties the knot, counter-knot, and additional knots correctly.	Y/N	249
8	Cuts the thread to the proper length using correct technique.	Y/N	206
9	Positions the knot lateral to the wound.	Y/N	199
10	Applies the correct degree of tension to the knot.	Y/N	209
11	Maintains appropriate distance between sutures.	Y/N	209
12	Performs suturing safely throughout the procedure.	Y/N	236
13	Safely stores suturing equipment and needle upon completion of the procedure.	Y/N	166
14	Executes the suture with dexterity, economy, and fluidity of movement.	Y/N	164
15	Demonstrates respect for tissues throughout the procedure.	Y/N	228
Global	Global Assessment Score	1 to 5	-

were introduced for discussion. Duplicates were removed, wording was standardized, and a consensus was reached on each item. The Delphi process consisted of three rounds, during which experts reviewed and discussed the items, offering feedback and assessing relevance. By the third round, consensus was achieved, and the final draft was collectively revised and approved by the group.

The final draft contained 15 yes/no items and a global performance scale with a Likert-type rating ranging from 1 to 5 (Table 1).

Step 3: Sample Size justification and application of the scale

We followed a 10:1 rule of thumb for determining the sample size,²⁸ which implied a minimum of 150 assessments, and used the Minho-SAS to evaluate the performance of 269 fifth-year medical students who underwent an objective structured clinical examination (OSCE) during a surgical clerkship. The assessments were carried out by six experienced medical doctors who were trained in the technique and had extensive experience in assessment.

Step 4: Psychometric analysis

The dimensionality of the assessment tool was evaluated using a comprehensive set of complementary psychometric methods. We began with parallel analysis, which helps determine the optimal number of dimensions by comparing the eigenvalues of our data against those from randomly generated datasets. This analysis was supplemented by the Bayesian information criterion (BIC), which helped evaluate different dimensional models by balancing model fit and complexity. To gain deeper insights into the unidimensional structure, we employed several specialized indices: unidimensional congruence (UniCo) and item unidimensional congruence (I-UniCo), which assess how well the data fit a single-dimension model at both the overall test and individual item levels; explained common variance (ECV) and item explained common variance (I-ECV), which quantify how much of the variance can be attributed to a primary dimension; and mean of item residual absolute loadings (MIREAL), which examines whether significant secondary dimensions exist. This multi-method approach provides robust evidence for the internal structure validity of the assessment tool, giving us confidence in our understanding of what the scale is measuring.

To obtain validity evidence based on the internal structure of the scale, we first conducted an item response theory analysis that included Rasch and two-parameter logistic (2-PL) models. Item parameters (difficulty and discrimination), item characteristic curves, and item information functions were estimated. Item fit was evaluated using infit and outfit statistics, with values between 0.5 and 1.5 considered

acceptable. The conditional reliability curve was generated to examine measurement precision across the ability spectrum.

Factor analysis of the tetrachoric correlation matrix was also performed, due to the dichotomic nature of the items. Due to the presence of asymmetric distributions in the items (as evidenced by skewness values ranging from -4.911 to -0.451), as well as extreme values for kurtosis (ranging from -1.793 to 22.032), a robust estimation method, robust diagonally weighted least squares (RDWLS), was employed for factor extraction. This method used robust mean and variance-scaled corrections for chi-square calculations. Bootstrapping with 1000 samples was used to obtain bias-corrected confidence intervals for key parameters. The rotation method was Robust Promin, using Weighted Varimax as the clever rotation start.

In addition to the validity based on internal structure, we aimed to obtain additional validity evidence based on:

- A) Test content: To assure content validity, adding to the approval of the previously described focus group, the scale was approved by additional expert medical professionals with experience in suture and psychometrics, ensuring scale alignment with the content.
- B) Response processes: To ensure the fit between the assessment process and the construct, assessors were subsequently questioned about their thought process, if they were evaluating suture skills, and if they thought they were assessing other competencies. Additionally, assessors were accompanied by surgical experts during the first assessments.
- C) Relations with other variables: To ensure the accuracy of the results, we used an established and validated technical assessment scale called objective structured assessment of technical skill (OSATS) in combination with the Minho-SAS.²⁹ This approach provided additional validity evidence to Minho-SAS and helped to enhance the validity of the findings. We conducted a correlation analysis and calculated Cohen's d between the test scores of the two assessed years to further validate the results.
- D) Consequences of testing: Following the analysis of the test scores, the faculty members responsible for the curricular unit blueprint and mapping can modify the curriculum to address possible gaps in students learning, as intended consequences of this exam. In the future, the scale can also be tested for feedback delivery.

We used Cronbach's alpha and McDonald's omega internal consistency coefficients and Rasch model scores' standard errors of measurement to estimate the reliability of the scale, in which coefficients above 0.70 were regarded as acceptable.²⁷

The analyses were performed using multiple software packages: Winsteps was used for the principal component analysis of Rasch model residuals (PCAR) and item-person maps. FACTOR version 12.02.01 was used for factor analysis of the tetrachoric correlation matrix and other dimensionality analyses and the R package *mirt* (R version 4.3.1) for the remaining Rasch and 2-PL model analyses. The R script used can be found in Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/23567/15832>). Classical reliability analyses using McDonald's omega and Cronbach's alpha coefficients and their confidence intervals were conducted using JASP (Version 0.18.1). Correlations between scores and Cohen's *d* coefficients were obtained using jamovi (v2.3.28).

RESULTS

The final Minho-SAS, composed of 15 dichotomous yes/no items and a global performance score ranging from 1 to 5, is presented in Table 1, with additional information regarding the number of positive assessments in the OSCE. The Minho-SAS is also available in Appendix 2 (Appendix 2: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/23567/15833>).

For the initial validation, the face-validation process was performed by showing the final prototype to experienced surgeons, with expertise on the skill to be assessed, with an unanimous positive judgement.

Dimensionality analysis

Factor analysis of the tetrachoric correlation matrix supported a unidimensional structure. The single-factor solution explained 39.96% of the total variance (eigenvalue = 5.99). Unidimensionality indices met established criteria: UniCo = 0.967 (95% CI: 0.968 - 0.979), ECV = 0.871 (95% CI: 0.875 - 0.884), and MIREAL = 0.184 (95% CI: 0.140 - 0.204). Model fit indices were adequate: RMSEA = 0.039 (90% CI: 0.000 - 0.058), CFI = 0.943 (95% CI: 0.875 - 1.190), and GFI = 0.911 (95% CI: 0.882 - 0.959). Factor loadings ranged from 0.213 to 0.822.

Q3 residual correlations from Rasch analysis were all below 0.3, supporting local independence. The principal component analysis of Rasch model residuals revealed an eigenvalue of 1.59 in the first contrast (i.e. the first residual component, suggesting essential unidimensionality. However, the Rasch model analysis explained 29.1% of the score variance, less than the factor analytical solution.

Factor analysis

Factor analysis model showed a fair fit to the data, with RMSEA = 0.039 (90% CI: 0.000 - 0.058), CFI = 0.943 (95% CI: 0.875 - 1.190), and GFI = 0.911 (95% CI: 0.882 - 0.959). Factor loadings ranged from 0.213 to 0.822, with most items showing moderate to high loadings [Appendix 3 (Appendix 3: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/23567/15834>)].

IRT analysis

The 2-PL analysis outperformed the Rasch model, as indicated by lower AIC, SABIC, HQ, and BIC values (Table 2). This suggests that the 2-PL model provides a significantly better fit, with a more favorable balance between model complexity and predictive accuracy. This conclusion is further supported by the significant chi-square value. Overall, the results from both models reinforce the validity of the scale based on its internal structure.

Difficulty and discrimination are key item parameters in IRT. According to Baker *et al*, item discrimination values of 0.01 - 0.34 are considered very low; 0.34 - 0.64: low; 0.65 - 1.34: moderate; 1.35 - 1.69: high; and 1.70 and above very high.³⁰ Difficulty represents the ability level at which an item has a 50% probability of being answered correctly, with higher values indicating more challenging items. Discrimination, on the other hand, reflects how well an item distinguishes between individuals of different ability levels, with higher values indicating that the item effectively differentiates between high and low performers.

In the Rasch model, item difficulty parameters range from -4.02 (item 3) to -0.587 (item 14), reflecting a wide distribution, suggesting that the Minho-SAS possesses items with progressive difficulty levels, which can be useful if we intend to assess different levels of proficiency. In the 2-PL analysis, the item difficulty values range from -4.388 (item 1) to -0.315 (item 14), corroborating Rasch's analysis. As for discrimination parameters, ranging from 0.525 (item 1) to 2.935 (item 14), items with higher values are more effective in distinguishing suture skills and contribute more to the Minho-SAS accuracy (Table 3). In this case, we have a broad spectrum of low to very high discrimination values, according to current literature.³¹

The item characteristic curves (ICCs) and information curves (IIC) for each item as estimated by the Rasch model and the 2-PL are depicted in Fig. 1. Each curve illustrates the probability of a correct response to the item at different

Table 2 – Model fit indices for Rasch and 2PL analyses of the Minho-SAS

	AIC	SABIC	HQ	BIC	logLik	χ^2	df	p
Rasch	3282.212	3288.997	3305.310	3339.727	-1625.106	NA	NA	NA
2PL	3261.493	3274.215	3304.802	3369.334	-1600.746	48.7191	14	< 0.0001

AIC: Akaike information criterion; SABIC: sample-size adjusted Bayesian information criterion; HQ: Hannan-Quinn information criterion; BIC: Bayesian information criterion; Df: degrees of freedom

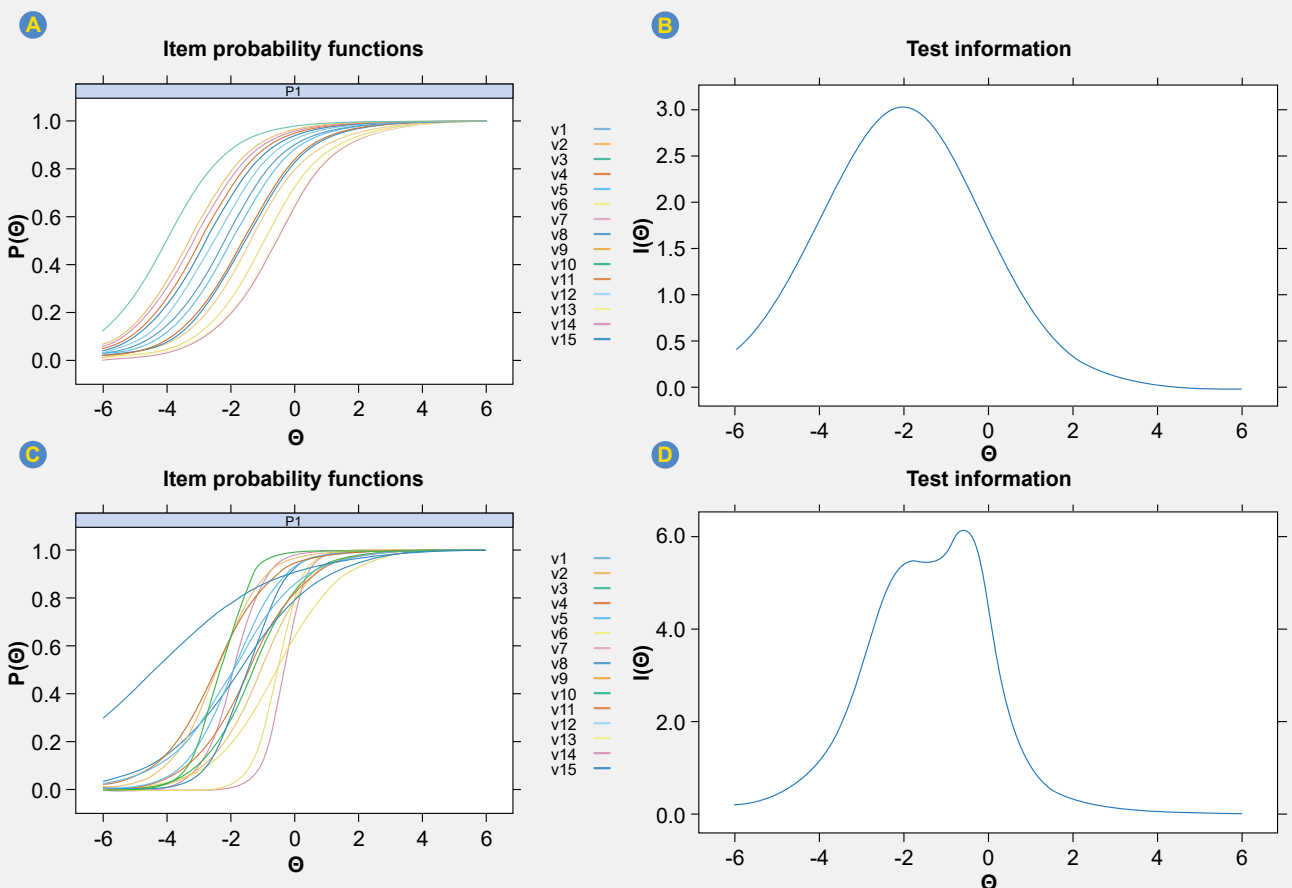


Figure 1 – Item characteristic and information curve for Rasch model (A and B) and for 2-PL model (C and D)

levels of the latent trait. The x-axis represents the latent trait continuum, indicating increasing levels of proficiency, while the y-axis shows the probability of endorsing the item. In these curves, it can be observed that, given a student whose value of Θ (theta) = 0, which would be an average student, the probability of having the item correctly would be 0.6 in item 14 (v14). When the probability is -2 Θ the value is almost 0.2 and when Θ is +4 the probability would be almost 1.

In ICC curves, item 3 exhibits a tall and narrow curve, indicating that it is very precise in measuring abilities, while item 6 has a broader ICC, suggesting that it provides information across a more comprehensive range of skills. Items with higher peaks (as item 3) are well suited for discriminating between individuals with similar abilities. The peak of the ICC represents the item's difficulty; item 2 peak is at a lower ability level, indicating that it is an easy item, while item 4 is at a higher ability level, indicating a more challenging item.

As for the IIC, the amount of information obtained from the Minho-SAS has its peak around $\Theta = -2$ at the Rasch

Analysis and $\Theta = 0$ at the 2-PL analysis, decreasing information when going out of this range of ability. This means that in the Rasch analysis, the Minho-SAS acquires the most informative measure for students with lower skill proficiency. The 2-PL analysis captures more detail in students with average ability.

Item fit statistics (Table 4) indicate how accurately the data fit the model. Outfit could be understood as a measure of how well an item matches a pattern of responses expected by the Rasch model. If the Outfit value is too high or too low, it could indicate that the item might be too difficult or too easy when compared with the prediction. Infit focuses on the consistency of responses, being more sensitive to the pattern of responses. If the value of infit is too high or too low, it should raise awareness that the item could be confusing or not aligned with the others. Fit values should be between 0.5 to 1.5,³² and values > 2.0 should be excluded.^{33,34} In our work, we observed that the outfit statistics range from 0.479 to 1.253, which indicates acceptable variability in the behavior of the items. Similarly, the infit statistics range from 0.954 to 1.247, suggesting good levels of

Table 3 – Difficulty and discrimination parameters for each item in Rasch and 2-PL models

	Rasch model	2-PL model	
	Difficulty	Difficulty	Discrimination
1	-2.8	-4.388	0.525
2	-3.32	-2.445	1.38
3	-4.02	-2.35	2.16
4	-2.95	-2.469	1.14
5	-1.98	-1.923	0.919
6	-0.948	-0.53	2.52
7	-3.18	-1.906	2.06
8	-1.55	-1.715	0.774
9	-1.37	-1.07	1.25
10	-1.63	-1.289	1.23
11	-1.63	-1.401	1.08
12	-2.52	-1.922	1.31
13	-0.628	-0.566	1.013
14	-0.587	-0.315	2.935
15	-2.21	-1.452	1.7

Table 4 – Item fit statistics for Rasch model

	outfit	infit
Minimum	0.479	0.954
Maximum	1.253	1.247
Mean	0.782	0.971
Standard Deviation	0.195	0.118

response consistency. The mean values for outfit (0.782) and infit (0.971) indicate an overall alignment of items with the Rasch model, though with some variability in their fit.

The item-person map (Fig. 2) illustrates the distribution of participants' latent scores (top portion) and item difficulty parameters (bottom portion). Most participants are concentrated on higher levels of ability, and most items are clustered in the lower-to-middle difficulty range, with only a few items positioned at higher difficulty levels. This aligns with the assumption and goal that the Minho-SAS is a better assessment method to detect those who are not proficient.

Reliability

The scale demonstrated good internal consistency, as evidenced by McDonald's ω estimate of 0.776 (95% CI: 0.736 - 0.815) and Cronbach's α of 0.765 (95% CI: 0.723 - 0.803). These values suggest a robust level of reliability, indicating that the items comprising the scale reliably measure the intended construct. The reliability coefficient obtained for the Rasch model (0.71) and 2-PL model (0.74) reflects an acceptable range for assessment.³¹

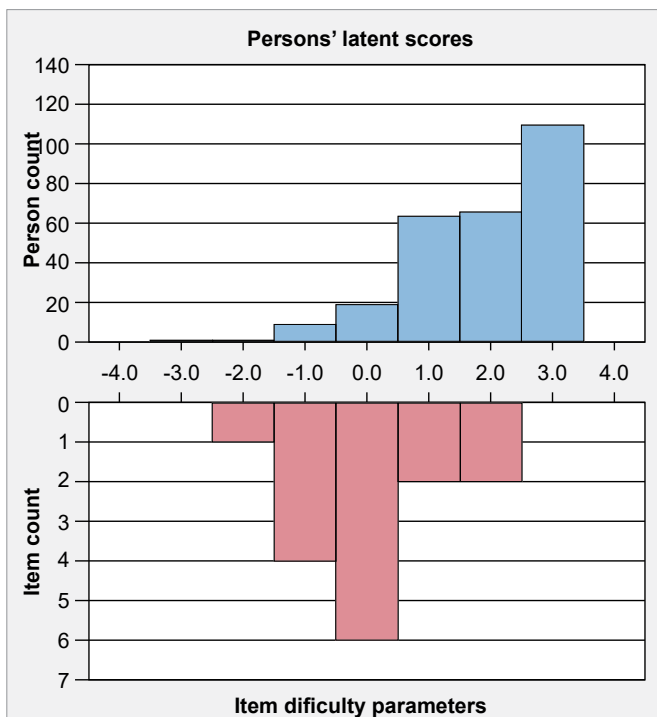
The conditional reliability plots obtained from both the

Rasch and the 2PL analyses (Fig. 3) give insights into the measurement precision of Minho-SAS across varying ability levels. In the Rasch model, the reliability is moderate level (around 0.4) for individuals with extremely low abilities (around -6 Θ). As abilities progress towards -3 to -0.5 Θ , the reliability significantly increases, stabilizing at a plateau of around 0.8. This indicates that the Rasch model is robust in measuring abilities consistently within this range. On the other hand, the 2-PL model demonstrates a notably improved trend but starts with lower reliability (less than 0.2) for those with the lowest abilities (-6 Θ). As abilities increase, the reliability swiftly improves, exceeding 0.8 around -2 Θ , and maintains this high precision up to $\Theta = 0$. This shows that the 2-PL model consistently and accurately measures abilities at these proficiency levels. These distinct reliability trends across ability levels highlight the validation mechanisms' effectiveness in ensuring precise measurement and offer valuable guidance for future refinements in assessment methodologies.

Validity based on relations with other variables

As for the correlation between the latent traits (theta), which represents the student ability, and the sum of the items from the Minho-SAS, there was an extremely high correlation level of 0.96 from 2PL and 0.982 from the Rasch model (Table 5).

The strong positive correlation between the Rasch and

**Figure 2** – Item-person map of Minho-SAS: distribution of participants' latent scores and item difficulty parameters

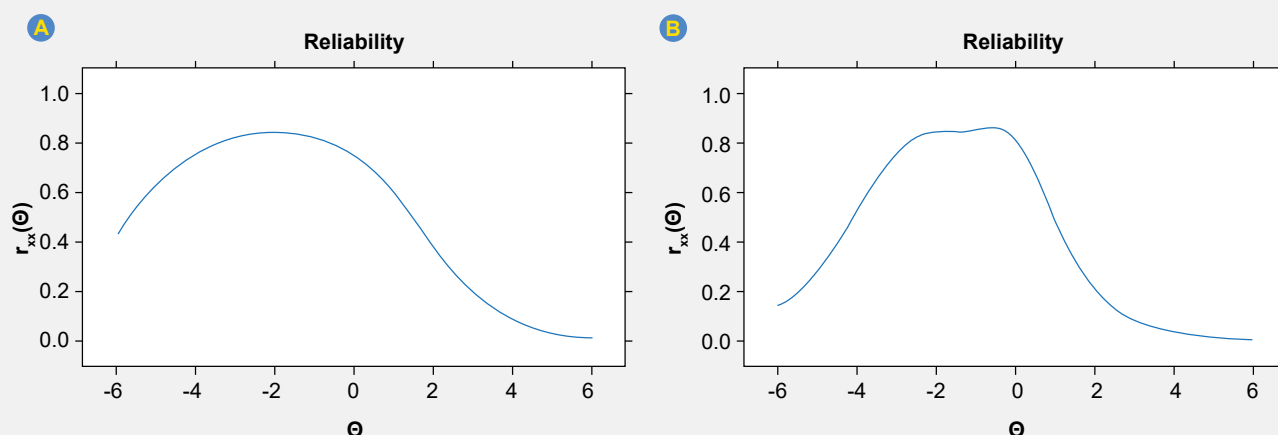


Figure 3 – Conditional reliability plot for Rasch (A) and (B) 2-PL analysis

2PL models ($r = 0.975$, $p < 0.001$) indicates a high agreement in measuring suturing skills. Additionally, their high correlations with the sum of Minho-SAS scores ($r = 0.982$ and $r = 0.960$, $p < 0.001$) reinforce the construct validity of the scale, as higher ability estimates align with higher total scores.

Moderate positive correlations between Minho-SAS scores and OSATS (Rasch: $r = 0.670$, 2PL: $r = 0.698$, $p < 0.001$) support its validation. However, an informatic error during the OSCE reduced the sample size ($df = 135$) for this analysis. The slightly lower correlations may reflect differences in item count and skill dimensions, with Minho-SAS capturing additional aspects of suturing skills. These strong associations further reinforce its validity as a robust assessment tool.

When searching for differences between the two assessed years, we conducted an independent samples t -test and a search for effect size using Cohen's d coefficient (Table 6).

The comparison between the assessed years reveals no difference in the Minho-SAS scores, suggesting that the scale demonstrates consistency across different cohorts of students. The observed effect sizes (Cohen's d) of 0.34 to 0.44, representing small to moderate effects, support this finding. Interestingly, there is a higher effect size on the global scale scores than the latent scores.

DISCUSSION

Suturing skills are essential for all medical graduates,

making their proper assessment crucial. The Minho-SAS addresses a specific gap in surgical skill assessment by focusing exclusively on basic suturing competencies for medical students. The development process, involving multi-specialty surgical experts, ensured content validity while avoiding specialty-specific bias. The choice of a dichotomous format over a Likert scale was informed by evidence that checklist assessments can match the precision of rating scales for specific technical skills while potentially improving feedback quality and ease of use. Current literature suggests that checklist scales can be used for assessing competencies without loss of measurement precision when compared to overall rating scales, especially when referring to specific competencies, such as suturing, and can even have advantages such as improving the quality of feedback and being more user-friendly.^{35,36}

The item response theory offers critical advantages for scale validation, as it models the relationship between an individual's latent trait (in this case, suturing skill) and their response to the individual items of Minho-SAS. This contrasts with the classical test theory, which considers all items as equivalents, not considering item difficulty and discrimination. For this investigation, we employed two IRT models, the Rasch model and the 2-PL, which are well-suited for validating dichotomous assessment scales. The Rasch model is a one-parameter model that assumes unidimensionality and focuses on a single latent trait, not influenced by other factors. Each item in this model has a difficulty parameter (b) that represents the point on the ability

Table 6 – Effect sizes (Cohen's d) for Minho-SAS

		Statistics	gl	p	Cohen's d
Minho-SAS global score	Student's t	3.64	267	<0.001	0.443
Sum of Minho-SAS	Student's t	2.80	267	0.005	0.342
2PL	Student's t	2.93	267	0.004	0.357
Rasch	Student's t	2.98	267	0.003	0.363

continuum at which individuals have a 50% probability of having a positive assessment. The 2-PL model is an extension of one-parameter models, having a discrimination (a) parameter, which allows quantifying the item's ability to discriminate between students with different ability levels.

The unidimensional structure confirmed by both factor analysis and Rasch model analysis suggests the scale measures a single, coherent construct of basic suturing ability. The wide range of item difficulties and discrimination parameters indicates the scale can differentiate between students across different proficiency levels, though it performs optimally at distinguishing lower to moderate skill levels. This aligns with the scale's primary purpose of identifying students who have not yet achieved basic competence.

The correlation between Minho-SAS and OSATS scores supports concurrent validity while highlighting their complementary nature. The OSATS provides a broader assessment of surgical skills, whereas Minho-SAS offers a detailed evaluation specific to basic suturing. The moderate correlation coefficients suggest these tools measure related but distinct aspects of surgical competence. The absence of time-based metrics in Minho-SAS represents a deliberate choice to focus on technique quality rather than speed, which may be more appropriate for assessing foundational competences.²¹

This study has several limitations. First, the sample was drawn from a single institution, which may limit the generalizability of the findings to the wider medical student population. Second, the high success rates observed across items suggest that the scale may have limited sensitivity in differentiating among highly proficient students. Nonetheless, this potential ceiling effect is less concerning given that the primary aim of the Minho-SAS is to identify minimum competence rather than to discriminate levels of excellence. Future versions of the scale might consider incorporating more challenging items to assess advanced performance, though such changes would need to remain aligned with the instrument's original purpose. Finally, the use of a single rater per student represents a methodological limitation. While rater training was implemented to mitigate variability, future applications should incorporate dual or multiple independent raters to enhance reliability and provide more robust evidence of inter-rater agreement.

The statistical evidence supports the validity and reliability of Minho-SAS for its intended purpose. The combination of different analyses provides complementary evidence for the scale's psychometric properties. The strong correlations between different scoring methods (raw scores, Rasch measures, and 2-PL estimates) indicate scoring consistency, while the conditional reliability analyses identify the abil-

ity ranges where the scale provides most precise measurement.

CONCLUSION

This study offers robust validity evidence supporting the Minho-SAS as a reliable instrument for assessing basic suturing skills in medical students. Psychometric analyses support a unidimensional internal structure and demonstrate strong reliability across various models, particularly in effectively identifying students who have yet to attain basic competences. While the scale is less precise at higher proficiency levels, this aligns with its primary purpose of certifying basic competences rather than advanced skills. Further studies are encouraged to explore its performance across diverse educational contexts and to investigate its potential use for formative assessment and targeted feedback. The Minho-SAS represents a meaningful step toward evidence-based assessment of core surgical skills, offering a solid foundation for future refinement and broader application.

ACKNOWLEDGMENTS

The authors have declared that no AI tools were used during the preparation of this work.

AUTHOR CONTRIBUTIONS

NSG, RMS: Study design, writing and critical review of the manuscript.

CC, VHP, JMP, MBA: Study design, critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

FUNDING SOURCES

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

REFERENCES

1. Ten Cate O, Khursigara-Slattey N, Cruess RL, Hamstra SJ, Steinert Y, Sternszus R. Medical competence as a multilayered construct. *Med Educ*. 2024;58:93-104.
2. Epstein RM, Hundert EM. Defining and assessing professional competence. *JAMA*. 2002;287:226.
3. Witheridge A, Ferns G, Scott-Smith W. Revisiting Miller's pyramid in medical education: the gap between traditional assessment and diagnostic reasoning. *Int J Med Educ*. 2019;10:191.
4. Frank JR, Danoff D. The CanMEDS initiative: implementing an outcomes-based framework of physician competencies. *Med Teach*. 2007;29:642-7.
5. Moskowitz EJ, Nash DB. Accreditation council for graduate medical education competencies: practice-based learning and systems-based practice. *Am J Med Qual*. 2007;22:351-82.
6. Ten Cate O. Entrustability of professional activities and competency-based training. *Med Educ*. 2005;39:1176-7.
7. Epstein RM. Assessment in medical education. Cox M, Irby DM, editors. *N Engl J Med*. 2007;356:387-96.
8. Emmanuel T, Nicolaidis M, Theodoulou I, Yoong W, Lymperopoulos N, Sideris M. Suturing skills for medical students: a systematic review. *In Vivo*. 2021;35:1-12.
9. Vaidya A, Aydin A, Ridgley J, Raison N, Dasgupta P, Ahmed K. Current status of technical skills assessment tools in surgery: a systematic review. *J Surg Res*. 2020;246:342-78.
10. Bilgic E, Endo S, Lebedeva E, Takao M, McKendy KM, Watanabe Y, et al. A scoping review of assessment tools for laparoscopic suturing. *Surg Endosc*. 2018;32:3009-23.
11. Almeland SK, Lindford A, Sundhagen HP, Hufthammer KO, Strandenes E, Svendsen HL, et al. The effect of microsurgical training on novice medical students' basic surgical skills - a randomized controlled trial. *Eur J Plast Surg*. 2020;43:459-66.
12. Dormegny L, Neumann N, Lejay A, Sauer A, Gaucher D, Proust F, et al. Multiple metrics assessment method for a reliable evaluation of corneal suturing skills. *Sci Rep*. 2023;13:2920.
13. Nugent E, Joyce C, Perez-Abadia G, Frank J, Sauerbier M, Neary P, et al. Factors influencing microsurgical skill acquisition during a dedicated training course. *Microsurgery*. 2012;32:649-56.
14. Chipman JG, Schmitz CC. Using objective structured assessment of technical skills to evaluate a basic skills simulation curriculum for first-year surgical residents. *J Am Coll Surg*. 2009;209:364.
15. Goova MT, Hollett LA, Tesfay ST, Gala RB, Puzziferri N, Kehdy FJ, et al. Implementation, construct validity, and benefit of a proficiency-based knot-tying and suturing curriculum. *J Surg Educ*. 2008;65:309-15.
16. Sato E, Mitani S, Nishio N, Kitani T, Sanada T, Ugumori T, et al. Development of proficiency-based knot-tying and suturing curriculum for otolaryngology residents: a pilot study. *Auris Nasus Larynx*. 2020;47:291-8.
17. Thinggaard E, Zetner DB, Fabrin A, Christensen JB, Konge L. A study of surgical residents' self-assessment of open surgery skills using gap analysis. *Simul Healthc*. 2023;18:305-11.
18. Buckley CE, Kavanagh DO, Gallagher TK, Conroy RM, Traynor OJ, Neary PC. Does aptitude influence the rate at which proficiency is achieved for laparoscopic appendectomy? *J Am Coll Surg*. 2013;217:1020-7.
19. Nickel F, Brzoska JA, Gondan M, Rangnick RM, Chu J, Kenngott HG, et al. Virtual reality training versus blended learning of laparoscopic cholecystectomy: a randomized controlled trial with laparoscopic novices. *Medicine*. 2015;94:e764.
20. Ebina K, Abe T, Hotta K, Higuchi M, Furumido J, Iwahara N, et al. Objective evaluation of laparoscopic surgical skills in wet lab training based on motion analysis and machine learning. *Langenbecks Arch Surg*. 2022;407:2123-32.
21. Sundhagen HP, Almeland SK, Hansson E. Development and validation of a new assessment tool for suturing skills in medical students. *Eur J Plast Surg*. 2018;41:207-16.
22. Vassiliou MC, Feldman LS, Andrew CG, Bergman S, Leffondré K, Stanbridge D, et al. A global assessment tool for evaluation of intraoperative laparoscopic skills. *Am J Surg*. 2005;190:107-13.
23. De Champlain AF. A primer on classical test theory and item response theory for assessments in medical education. *Med Educ*. 2010;44:109-17.
24. Bond T, Yan Z, Heene M. Applying the Rasch model: fundamental measurement in the human sciences. 4th ed. New York: Routledge; 2020.
25. Tavakol M, Dennick R. The foundations of measurement and assessment in medical education. *Med Teach*. 2017;39:1010-5.
26. American Educational Research Association, American Psychological Association, National Council on Measurement in Education. Standards for Educational and Psychological Testing. 2014. [cited 2024 Feb 06]. Available from: https://www.testingstandards.net/uploads/7/6/6/4/76643089/standards_2014edition.pdf.
27. Boateng GO, Neilands TB, Frongillo EA, Melgar-Quinonez HR, Young SL. Best practices for developing and validating scales for health, social, and behavioral research: a primer. *Front Public Health*. 2018;6:1-18.
28. Goodhue DL, Lewis W, Thompson R. Does PLS have advantages for small sample size or non-normal data? *MIS Q*. 2012;36:981-1001.
29. Martin JA, Regehr G, Reznick R, MacRae H, Murnaghan J, Hutchison C, et al. Objective structured assessment of technical skill (OSATS) for surgical residents. *Br J Surg*. 1997;84:273-8.
30. Baker FB. The basics of item response theory. 2nd ed. 2001. [cited 2025 Mar 23]. Available from: <https://eric.ed.gov/?id=ED458219>.
31. Walsh A, Cao R, Wong D, Kantschuster R, Matini L, Wilson J, et al. Using item response theory (IRT) to improve the efficiency of the Simple Clinical Colitis Activity index (SCCAI) for patients with ulcerative colitis. *BMC Gastroenterol*. 2021;21:132.
32. Institute for Objective Measurement. What do infit and outfit, mean-square and standardized mean? [cited 2023 Nov 16]. Available from: <https://www.rasch.org/rmt/rmt162f.htm>.
33. Cecilio-Fernandes D, Medema H, Collares CF, Schuwirth L, Cohen-Schotanus J, Tio RA. Comparison of formula and number-right scoring in undergraduate medical training: a Rasch model analysis. *BMC Med Educ*. 2017;17:192.
34. Institute for Objective Measurement. Dichotomous mean-square fit statistics. [cited 2023 Nov 16]. Available from: <https://www.rasch.org/rmt/rmt82a.htm>.
35. Wood TJ, Pugh D. Are rating scales really better than checklists for measuring increasing levels of expertise? *Med Teach*. 2020;42:46-51.
36. Ilgen JS, Ma IW, Hatala R, Cook DA. A systematic review of validity evidence for checklists versus global rating scales in simulation-based assessment. *Med Educ*. 2015;49:161-73.

Cleft Lip and Palate: Prenatal Diagnosis, Genetic Testing, and Pregnancy Outcomes in a Tertiary Referral Center

Fenda Lábio-Palatina: Diagnóstico Pré-Natal, Estudo Genético e Desfechos da Gravidez num Centro Terciário de Referência

Helena DIAS ^{1,2}, Diogo FERNANDES DA ROCHA ³, Marta HENRIQUES COSTA ^{1,2}, Susana GUIMARÃES ^{4,5}, Ana COSTA BRAGA ^{4,5}, Renata OLIVEIRA ³, Teresa CARRACA ^{1,2}, Marina MOUCHO ^{1,2}, Carla PINTO MOURA ^{6,7,8}, Magda MAGALHÃES ^{1,2},
Acta Med Port 2026 Jan;**39**(1):33-40 ▪ <https://doi.org/10.20344/amp.23371>

ABSTRACT

Introduction: Orofacial clefts are common congenital malformations that may occur in isolation or as part of a syndrome. Early prenatal diagnosis provides crucial information for parental counseling, delivery planning, and multidisciplinary neonatal care. This study aimed to review orofacial cleft cases diagnosed during the prenatal period and to assess the relationship between cleft type, associated anomalies, genetic findings and pregnancy outcomes.

Methods: This retrospective study included all fetuses with a prenatal diagnosis of cleft lip and/or cleft palate who received obstetric care at the Unidade Local de Saúde São João between January 2014 and December 2023. Data collected included baseline maternal characteristics, fetal sex, gestational age at diagnosis, associated anomalies, genetic and pathological evaluation and pregnancy outcomes.

Results: Forty-eight fetuses were included. Prenatal diagnosis was most often made in the second trimester (77.1%), while all first-trimester diagnoses were associated with additional anomalies. Overall, 20 fetuses (41.7%) had syndromic or non-isolated clefts, accounting for all chromosomal and genetic abnormalities. In isolated cases (58.3%), genetic testing consistently yielded normal results, with only two of them receiving a genetic diagnosis postnatally. Eighteen pregnancies were terminated, mostly in cases with associated anomalies.

Conclusion: In this single-center retrospective case series, chromosomal and genetic abnormalities were only detected in fetuses with syndromic clefts or additional anomalies. Among isolated cases, genetic testing was uniformly normal. These results reinforce that prenatal genetic testing may be most valuable when syndromic features or a strong family history are present, rather than as a routine in isolated clefts. Further multicenter studies are needed to support this approach and define standardized protocols.

Keywords: Cleft Lip; Cleft Palate; Congenital Abnormalities/diagnosis; Genetic Testing; Pregnancy Outcome; Prenatal Diagnosis

RESUMO

Introdução: As fendas lábio-palatinas são malformações congénitas frequentes que podem ocorrer isoladamente ou em associação com outras malformações. O diagnóstico pré-natal precoce é fundamental para o aconselhamento parental, planeamento do parto e organização de cuidados neonatais multidisciplinares. O objectivo deste estudo foi rever os casos de fenda lábio-palatina diagnosticados no período pré-natal e avaliar a relação entre o tipo de fenda, malformações associadas, achados genéticos e desfechos da gravidez.

Métodos: Este estudo retrospectivo incluiu todos os fetos com diagnóstico pré-natal de fenda labial e/ou palatina acompanhados na Unidade Local de Saúde São João entre janeiro de 2014 e dezembro de 2023. Foram recolhidos os dados relativos a características maternas, sexo fetal, idade gestacional ao diagnóstico, malformações associadas, testes genéticos e estudo anatomopatológico e desfechos da gravidez.

Resultados: Foram incluídos 48 fetos. O diagnóstico pré-natal foi realizado maioritariamente no segundo trimestre (77,1%), sendo que todos os diagnósticos no primeiro trimestre estavam associados a outras anomalias. No total, 20 fetos (41,7%) apresentavam fendas síndrómicas ou não isoladas, correspondendo a todos os casos com alterações cromossómicas ou genéticas neste estudo. Nos casos de fenda isolada (58,3%), os testes genéticos foram sempre normais, tendo-se identificado apenas duas anomalias adicionais no período pós-natal. Dezoito gravidezes foram interrompidas, essencialmente nos casos com malformações associadas.

Conclusão: Nesta série de casos retrospectiva, as alterações cromossómicas e genéticas foram identificadas apenas nos casos de fendas síndrómicas ou com malformações adicionais. Nos casos isolados, os testes genéticos foram invariavelmente normais. Estes resultados reforçam que a realização de testes genéticos pré-natais pode ser mais útil quando existem malformações associadas ou história familiar relevante. São necessários estudos multicéntricos para validar esta abordagem e definir protocolos estandardizados.

Palavras-chave: Anomalias Congénitas/diagnóstico; Diagnóstico Prenatal; Fenda Labial; Fenda Palatina; Resultado da Gravidez; Testes Genéticos

1. Obstetrics Department. Centro Hospitalar Universitário de São João. Unidade Local de Saúde de São João. Porto. Portugal.

2. Department of Gynecology and Obstetrics. Faculdade de Medicina. Universidade do Porto. Porto. Portugal.

3. Human Genetics Department. Centro Hospitalar Universitário de São João. Unidade Local de Saúde de São João. Porto. Portugal.

4. Department of Pathology. Centro Hospitalar Universitário de São João. Unidade Local de Saúde de São João. Porto. Portugal.

5. Department of Pathology. Faculdade de Medicina. Universidade do Porto. Porto. Portugal.

6. Otorhinolaryngology Department. Centro Hospitalar Universitário de São João. Unidade Local de Saúde de São João. Porto. Portugal.

7. Genetics Department. Department of Pathology. Faculdade de Medicina. Universidade do Porto. Porto. Portugal.

8. RISE-Health. Department of Pathology. Faculdade de Medicina. Universidade do Porto. Porto. Portugal.

✉ **Autor correspondente:** Helena Dias. helenacarolinadas@gmail.com

Recebido/Received: 20/05/2025 - **Aceite/Accepted:** 14/10/2025 - **Publicado Online/Published Online:** 19/12/2025 - **Publicado/Published:** 02/01/2026

Copyright © Ordem dos Médicos 2026



KEY MESSAGES

- Most orofacial clefts were diagnosed during the second trimester.
- Syndromic cases were diagnosed earlier.
- Genetic alterations were found only in syndromic cases.
- Isolated clefts had a high prenatal-postnatal diagnostic concordance.
- Genetic testing should be reserved for syndromic or familial cases.

INTRODUCTION

Orofacial clefts, which include cleft lip (CL), without or with cleft palate (CLP) or cleft palate alone (CP), are one of the most common congenital malformations, affecting approximately 1 to 2.2/1000 live births.¹ These anomalies result from failure in the fusion of the nasal and maxillofacial processes between the 6th and 8th week of embryogenesis.²

Earlier prenatal diagnosis of orofacial clefts can be achieved by targeted examination of the retronasal triangle and the maxillary gap during the 1st trimester ultrasound.³ However, isolated findings are often only identified during the 2nd or 3rd trimester.

Most orofacial clefts are sporadic and multifactorial. Chromosomal abnormalities, such as trisomies 13 and 18, and monogenic disorders, account for most syndromic cases. In non-syndromic familial cases, monogenic causes are responsible for up to 10%,⁴ typically showing autosomal dominant inheritance with reduced penetrance and variable expressivity.⁵ The most common associated anomalies are congenital heart defects (31.1%).⁶⁻⁸

Most cases of CL and/or CP result from a complex interplay between environmental and genetic factors during the initial weeks of pregnancy. Maternal age, drugs (e.g. antiepileptic agents or corticosteroids), smoking and alcohol consumption during pregnancy, obesity, diabetes *mellitus*, and folate deficiency are among the environmental factors that can impact fetal development and increase the risk of facial cleft.⁹ Polymorphisms inherited from either parent can also contribute to that outcome or increase an individual's susceptibility.¹⁰

The newborn prognosis depends on the presence of associated malformations, which is determined by the accuracy of prenatal diagnosis. The prenatal diagnosis of orofacial cleft plays a central role in preparing families and optimizing neonatal care (e.g., chosen location for labor, an adequate multidisciplinary team, and organized surgical teams for timely interventions) to improve postnatal outcomes.

The aim of this study was to review orofacial cleft cases diagnosed during the prenatal period and to assess the relationship between cleft type, associated anomalies, genetic findings and pregnancy outcomes.

METHODS

This retrospective case series included all fetuses with

prenatal diagnosis of CL and/or CP managed at a tertiary university hospital in Porto (Unidade Local de Saúde São João) between January 2014 and December 2023.

All the cases with an antenatal suspicion of CL and/or CP were included; cases could be diagnosed in our center or referred from other centers at any gestational age.

Cases were identified through a search on a dedicated departmental electronic database with cases prospectively collected, weekly updated, and created in our prenatal diagnosis clinic. Additional data were retrieved from hospital-based electronic records, including: Obscare® – Virtual Care (Porto, Portugal) and SClínico® – SPMS (Lisbon, Portugal). Ultrasound data were obtained from the ASTRAIA® software. Following a review of the medical records, the collected data included maternal characteristics (age, gravidity, parity, body mass index, and family history), fetal characteristics (sex, gestational age at diagnosis, presence of other fetal malformations, genetic evaluation) and pregnancy outcomes (gestational age and birth weight at delivery, termination of pregnancy) and, when applicable, pathological examination findings. When available, newborn examinations and pathology reports were reviewed to identify anomalies not detected antenatally.

Cases lost to follow-up were excluded.

This study was approved by the institutional ethics committee of Unidade Local de Saúde de São João [CES-OP-11-2025].

RESULTS

The study enrolled 48 fetuses with a CL and/or CP prenatal diagnosis (Table 1).

Gestational age at diagnosis

These anomalies were diagnosed at different stages of pregnancy (Table 1). Ten cases (20.8%) were identified in the first trimester, 37 cases (77.1%) in the second trimester, and one case (2.1%) in the third trimester. All fetuses diagnosed in the first trimester had additional malformations.

Syndromic/non-isolated clefts

A total of 20 fetuses (41.7%) were found to have other structural anomalies on ultrasound, and all chromosomal anomalies or genetic variants were identified within this

group. Among these cases, two had CP, while the remaining cases involved CLP. Regarding laterality, 12 presented with unilateral clefts, five with bilateral clefts, and three with midline clefts – representing all the midline clefts in this study.

Chromosomal abnormalities (n = 12): Trisomy 13 was identified in eight fetuses and trisomy 18 in four, accounting

for 60.0% of cases with additional anomalies and 25.0% of all cases.

Non-trisomic cases (n = 8): In the eight non-trisomic cases, cardiac malformations were present in all, while central nervous system anomalies, skeletal defects, and abdominal wall anomalies were each observed in one case. Targeted or advanced genetic testing revealed:

Table 1 – Clinical characteristics of the study groups

Patients' Characteristics	Associated malformations n (%)	Isolated orofacial cleft n (%)	Total cases
Number of cases	20 (41.7%)	28 (58.3%)	48
General			
Maternal age at diagnosis (years) ± SD	34.1 ± 6.0	31.4 ± 5.7	32.5 ± 5.9
Gravidity ± SD	2.1 ± 1.4	2.5 ± 1.7	2.3 ± 1.6
Parity ± SD	0.7 ± 0.9	1.1 ± 1.4	0.9 ± 1.2
Body mass index (kg/m ²) ± SD	24.2 ± 4.2	26.5 ± 6.2	25.6 ± 5.5
Family history	0	9 (32.1%)	9 (18.8%)
Fetal sex			
Male	10 (50.0%)	19 (67.9%)	29 (60.4%)
Female	10 (50.0%)	9 (32.1%)	19 (39.6%)
Time of ultrasound diagnosis			
1 st trimester	10 (50.0%)	0	10 (20.8%)
2 nd trimester	9 (45.0%)	28 (100%)	37 (77.1%)
3 rd trimester	1 (5.0%)	0	1 (2.1%)
Type of cleft			
Cleft lip	0	6 (21.4%)	6 (12.5%)
Cleft palate	2 (10.0%)	0	2 (4.2%)
Cleft lip and palate	18 (90.0%)	22 (78.6%)	40 (83.3%)
Cleft laterality			
Unilateral	12 (60.0%)	20 (71.4%)	32 (72.9%)
Bilateral	5 (25.0%)	8 (28.6%)	13 (27.1%)
Midline	3 (15.0%)	0	3 (6.25%)
Genetic testing			
QF-PCR	20 (100%)	22 (78.6%)	42 (87.5%)
Karyotype	13 (65.0%)	3 (10.7%)	15 (31.3%)
Microarray analysis	7 (35.0%)	19 (67.8%)	26 (54.2%)
Orofacial cleft panel	2 (10.0%)	2 (7.1%)	4 (8.3%)
Whole exome sequencing	3 (15.0%)	0	3 (6.25%)
Not performed	0	6 (20.7%)	6 (12.5%)
Pregnancy outcome			
Medical termination of pregnancy	16 (80.0%)	2 (7.1%)	18 (37.5%)
Intrauterine fetal demise	1 (5.0%)	0	1 (2.1%)
Alive fetus	3 (15.0%)	26 (92.9%)	29 (60.4%)
Gestational age at birth (w)	38.6 ± 1.3	38.7 ± 2.2	38.7 ± 2.0
Birth weight (g ± SD)	2863 ± 344 g	3143 ± 491 g	3100 ± 468 g

- *WDPCP*-related disorder: a fetus with unilateral CLP, pre-axial polydactyly in both feet and the left hand, bilateral brachydactyly, atrioventricular septal defect, and an aberrant subclavian artery was diagnosed prenatally. Karyotype and microarray results were normal, but whole exome sequencing identified a pathogenic *WDPCP* variant, confirmed postnatally (Table 2, case 14).
- Pathogenic variant in the *ABCA4* gene: a fetus with bilateral CLP, cardiomyopathy and early growth restriction had a heterozygous pathogenic variant in the *ABCA4* gene identified on a targeted gene panel (Table 2, case 16).
- Pathogenic variant in the X-linked *STAG2* gene: a male fetus with a small trabecular ventricular sept defect (VSD) as the sole finding (Table 2, case 20) was found to have a *de novo* pathogenic variant in the X-linked *STAG2* gene, leading to pregnancy termination. The postmortem pathological study confirmed the diagnosis of complete bilateral CLP and VSD, and additionally, identified a thoracic hemivertebra and minor anomalies in the lower limbs.
- Wiedemann-Steiner syndrome: this case involved a pregnant woman with epilepsy, treated with clobazam and carbamazepine. The prenatal ultrasound revealed CP, corpus callosum agenesis, and Fallot's tetralogy. Prenatal genetic testing (QF-PCR and microarray) was normal, but the postnatal evaluation was consistent with Wiedemann-Steiner syndrome, which was confirmed by genetic testing (Table 2, case 15).

Pregnancy outcomes: among the 20 fetuses with additional anomalies, 16 pregnancies were medically terminated, including eight in the first trimester. Of the four ongoing pregnancies, one fetus affected by trisomy 13 experienced fetal demise at 37 weeks of gestation.

Isolated clefts

Of the 28 fetuses (58.3%) diagnosed with isolated orofacial clefts, all were detected in the second trimester, between 19 and 23 weeks of gestation.

Regarding maternal and family history, nine cases (32.1%) had a family history of facial clefts. Folic acid supplementation was reported in three women before conception, in 15 during the first trimester, while three did not take folic acid; data were unavailable for seven cases. Maternal age ≥ 35 years was observed in nine cases (32.1%), and maternal obesity (BMI ≥ 30 kg/m²) was present in ten cases (35.7%).

With respect to subtype distribution, 22 fetuses (78.6%) had cleft lip and palate (CLP), including 14 unilateral and eight bilateral cases, while six fetuses (21.4%) presented

with unilateral cleft lip (CL) only. Of the 28 fetuses, 19 were male (67.8%) and nine female (32.1%).

Genetic testing was performed in 22/28 cases. In 19 cases (67.9%), QF-PCR followed by microarray analysis yielded normal results. A targeted gene panel was conducted in two pregnancies, both with negative findings, while in three cases only a karyotype was performed, also without abnormalities.

Pregnancy outcomes were favorable in most cases: 26 pregnancies continued to term. Two pregnancies were electively terminated upon parental request, and in both cases histopathological analysis confirmed unilateral or bilateral CLP without additional anomalies.

DISCUSSION

Orofacial clefts are a significant category of fetal malformations due to their diagnostic, therapeutic, and prognostic complexities. This highlights the critical role of prenatal diagnosis in ensuring timely referral and appropriate management of orofacial clefts by a multidisciplinary healthcare team.

Time of diagnosis

In this study, the gestational age at diagnosis ranged from 11 to 34 weeks, with most of the diagnoses occurring during the second trimester ultrasound. However, when other structural malformations were simultaneously present with orofacial cleft, the diagnostic yield of ultrasound in the first trimester was markedly higher, reaching 50.0%.

Although prenatal diagnosis is often established during the second trimester, some ultrasound signs can predict orofacial clefts as early as 11 to 13 weeks of gestation,¹¹⁻¹³ with higher reliability at 13 to 14 weeks.¹⁴ During this period, the main ultrasound features described in the literature that may suggest an underlying cleft lip and palate include: an abnormal configuration of the retronasal triangle in both the coronal and midsagittal views, a maxillary gap, absence of the superimposed-line sign, and a palatine-maxillary diameter below the 5th percentile.^{13,15-17} For bilateral clefts, assessment of the integrity of the fetal profile is crucial.

In the second trimester, the main findings were the discontinuity in the soft tissues of the upper lip, with or without discontinuity of the alveolar ridge, in a coronal and axial plane, respectively. Color Doppler ultrasonography can also be helpful, especially in detecting fetal hard palate clefts.¹²

For high-risk populations, three-dimensional ultrasound significantly enhances diagnostic sensitivity, with the added benefit of allowing parents to clearly visualize the specific type of malformation.^{15,18,19}

Associated anomalies

In our cohort, 41.7% of fetuses with orofacial cleft had

Table 2 – Description of the cases with ultrasound diagnosis of orofacial cleft and associated malformations. For each case, gestational age at diagnosis, genetic diagnosis (when established), and pregnancy outcomes are also included.

Case	Cleft malformation description and associated findings	Gestational age at diagnosis (weeks)	Genetic testing	Outcome
1	Unilateral cleft lip and palate, fetal growth restriction, hypoplastic kidneys, overlapping fingers	21	Trisomy 18	TOP (22w)
2	Bilateral cleft lip and palate, brachycephaly, corpus callosum agenesis, microphthalmia, micrognathia, hypotelorism, diaphragmatic hernia, interventricular communication, polydactyly, hypospadias	13	Trisomy 13	IUFD at term (37w)
3	Midline cleft lip and palate, holoprosencephaly, omphalocele	12	Trisomy 13	TOP (12w)
4	Bilateral cleft lip and palate, choroid plexus cysts, absent stomach, renal duplication, closed hands with overlapping fingers	21	Trisomy 18	TOP (22w)
5	Cleft palate, omphalocele, pericardial effusion, atrioventricular septal defect, syndactyly	13	Trisomy 18	TOP (14w)
6	Medline cleft lip and palate, holoprosencephaly	12	Trisomy 18	TOP (12w)
7	Unilateral cleft lip and palate, holoprosencephaly, omphalocele, large and hyperechogenic kidneys, skin edema, polydactyly	13	Trisomy 13	TOP (13w)
8	Unilateral cleft lip and palate, fetal hydrops, complex cardiomyopathy	13	Trisomy 13	TOP (13w)
9	Unilateral cleft lip and palate, holoprosencephaly, omphalocele, hypoplastic left heart	12	Trisomy 13	TOP (13w)
10	Unilateral cleft lip and palate, holoprosencephaly, hypotelorism, complex cardiomyopathy, single umbilical artery	11	Trisomy 13	TOP (12w)
11	Unilateral cleft lip and palate, omphalocele, hypoplastic left heart, single umbilical artery	11	Normal karyotype	TOP (14w)
12	Unilateral cleft lip and palate, Dandy-Walker malformation, bilateral ureteral stenosis, overlapping fingers, single umbilical artery	18	Trisomy 13	TOP (18w)
13	Midline cleft lip and palate, double-outlet left ventricle	16	Normal QF-PCR and microarray	TOP (18w)
14	Unilateral cleft lip and palate, atrioventricular communication, polydactyly, brachydactyly	20	Normal QF-PCR and microarray. <i>WDPCP</i> -related disorder (prenatal exome)	Alive
15	Cleft palate, corpus callosum agenesis, bilateral ventriculomegaly, Fallot tetralogy/double-outlet right ventricle, retrognathia	35	Wiedemann-Steiner syndrome, heterozygous pathogenic variant in <i>KMT2A</i> (postnatal exome)	Alive
16	Bilateral cleft lip and palate, fetal growth restriction, cardiomyopathy	24	Normal QF-PCR and microarray, heterozygous pathogenic variant in <i>ABCA4</i> (cleft panel)	Alive
17	Unilateral cleft lip and palate, abdominal cyst, complex cardiomyopathy, single umbilical artery	12	Normal QF-PCR and microarray	TOP (16w)
18	Unilateral cleft lip and palate, atrioventricular communication, distended jugular lymphatic sacs	16	Normal QF-PCR and microarray	TOP (17w)
19	Bilateral cleft lip and palate, cerebellar hypoplasia, hyperechoic kidneys; disproportion of the cardiac chambers, with predominance of the right chambers.	16	Trisomy 13	TOP (20w)
20	Bilateral cleft lip and palate, small trabecular ventricular septal defect	21	Normal QF-PCR and microarray, <i>de novo</i> pathogenic variant in <i>STAG2</i> (prenatal exome)	TOP (24w)

TOP: termination of pregnancy; IUFD: intrauterine fetal demise; w: weeks

associated anomalies. All cases presented with CLP, except for two cases involving CP alone.

Previous studies have reported non-isolated clefts in around 30%,^{1,2} with a wide range of associated anomalies.^{20,21} For example, in a case series of 45 fetuses with orofacial clefts, 35.6% of these cases also had additional anomalies.² Another multicenter study of 35 924 non-selected pregnancies, identified 62 cases of orofacial clefts, 39% of which had associated defects.²²

Sixty percent (12/20) were trisomies (T13 and T18), a trend consistent with the literature, where trisomies are most prevalent in cases of CLP and CP.²²

Among our eight non-trisomic cases, the most frequent anomalies were in the cardiovascular system, followed by the musculoskeletal and central nervous systems. According to the literature, excluding trisomies, the anomalies most commonly associated with CL and/or CP involve the cardiovascular, musculoskeletal, and central nervous systems.²³

Genetic testing: yield and interpretation

In our study, all genetic findings were confined to syndromic cases, with all isolated cleft cases yielding consistently normal results. Our findings are consistent with the literature, emphasizing a higher frequency of genetic diagnosis in non-isolated orofacial clefts.^{23,24}

Trisomies were the most frequent diagnosis (60%). In the remaining cases, the etiology was not diagnosed prenatally using karyotyping and/or microarray. However, whole exome sequencing (WES) was performed in three fetuses with additional anomalies and provided a definitive diagnosis in all: WDPCP-related disorder (Table 2, case 14), an *ABCA4*-related disorder (Table 2, case 16), and Wiedemann-Steiner syndrome caused by a *KMT2A* pathogenic variant (Table 2, case 15). Recent literature, however, suggests a more modest diagnostic yield of WES in prenatal cohorts. For example, Basha *et al* reported a yield of around 10% in familial non-syndromic clefts.⁴

In one case, a heterozygous pathogenic variant in the *ABCA4* gene, typically associated with Stargardt disease, was identified using a target gene panel. However, recent literature suggests that polymorphisms in this gene may increase susceptibility to CL and/or CP. These associations, primarily derived from genome-wide association studies, should be interpreted cautiously (Table 2, case 16).^{25,26}

Only one case received a postnatal diagnosis: Wiedemann-Steiner syndrome, identified via exome sequencing (Table 2, case 15). This syndrome has been reported in 3% of cases with submucous cleft palate.²⁷ However, the potential clefting effect of anti-epileptic drugs taken during pregnancy should also be considered.²⁸ A future epigenature study could help differentiate the influence of these two

factors.

In most cases of suspected isolated orofacial clefts, QF-PCR and microarray were primarily offered, all yielding normal results. The three cases that underwent only karyotype analysis were referred to our center after the chromosomal study, at or after 25 weeks of gestation. Six cases chose not to undergo prenatal genetic testing. Further genetic analysis using specific panels for clefts was conducted in two cases, based on individual clinical decisions, and exome sequencing was not performed. Among all the genetic tests performed no significant abnormalities were found.

These results raise several important questions regarding prenatal genetic testing. How extensive should prenatal genetic testing be, especially in cases of isolated orofacial cleft? In isolated cases, particularly if unilateral, would it not be more relevant to complete genetic testing (panel or exome) in the postnatal period, tailoring the study based on additional findings or family history? This approach may be crucial for developing more universal and consistent genetic testing strategies⁵ that both ensure the quality of prenatal diagnosis and address complex and often challenging outcomes of genetic testing.

Genetic testing in isolated orofacial cleft also presents significant ethical dilemmas. Nearly all cases yield normal results,^{5,29} which can delay decision-making beyond the legal time frame for pregnancy termination in Portugal (24 weeks of gestation). Notably, genetic testing, particularly targeted NGS panels or whole-exome sequencing (WES), can take several weeks to complete. Consequently, even if a relevant genetic alteration is identified, it might be reported after the optimal time frame. Additionally, many findings may lack clear prognostic value, as many variants associated with isolated orofacial clefts often exhibit incomplete penetrance and clinical heterogeneity.²⁹ This suggests that limiting prenatal genetic testing to syndromic cases or those with a strong family history may be a more appropriate approach.

Pregnancy outcomes

In our series, 18 out of a total of 48 cases resulted in the termination of pregnancy, with only two cases involving an isolated orofacial cleft.

In the 28 cases of presumed isolated facial cleft, additional malformations were detected postnatally in two cases. In the first case, the postnatal evaluation revealed left macroglossia (lymphatic malformation), and in the second case, hypospadias were identified. This corresponds to a 7.1% rate of undiagnosed anomalies in cases with CL and/or CP, which is much lower than the 35.5% reported in the literature.²

During childhood, one child was diagnosed with autism spectrum disorder. Before the diagnosis, both microarray

and cleft panel analyses were performed, yielding normal results, and the family was waiting for a genetics consultation.

In another case, a newborn presented with asymmetrical macroglossia, prompting microarray analysis, which also returned normal results.

Parental impact and counselling

Diagnosing an orofacial cleft during prenatal ultrasound can indeed have a profound emotional impact on the parents, often becoming a heavy burden. This emotional strain is intensified by the understanding that prenatal evaluation may not always detect all associated anomalies, making it challenging to predict the full extent of the prognosis. As a result, the decision to continue or terminate the pregnancy becomes more difficult and emotionally charged. However, based on our case series, we found that ensuring an excellent prenatal diagnosis can significantly reduce the percentage of cases with postnatal diagnoses of additional anomalies. This highlights the importance of comprehensive and accurate prenatal screening, as it can provide more clarity for parents and better guide decision-making during such a difficult time. The benefits of prenatal diagnosis extend far beyond the detection of an orofacial cleft, playing a crucial role in providing parents with the necessary information to understand their options and plan for postnatal care. This early communication allows parents to prepare emotionally and practically, improving their adherence to recommended treatments and interventions, which ultimately benefits the child's well-being.

A multidisciplinary team – including obstetricians, geneticists, neonatologists/pediatricians, pediatrics and plastic surgeons, stomatologists, otolaryngologists, physiatrists, speech therapists, nutritionists, and psychologists – is essential for the comprehensive management of orofacial malformations. This collaborative approach ensures the best possible outcomes for both the child and the parents, addressing the physical, emotional, and social aspects of care.

Limitations

We acknowledge some limitations in our study, such as its retrospective nature and the lack of assessment of postnatal cases of orofacial cleft without a prenatal diagnosis, mainly clefts of the secondary palate.

CONCLUSION

This retrospective case series highlights the importance of an accurate prenatal diagnosis of orofacial clefts, which

was most often achieved in the second trimester but could be established earlier in the presence of associated anomalies. Syndromic cases accounted for all genetic abnormalities and had a markedly higher rate of termination, whereas isolated clefts were usually carried to term with favorable neonatal outcomes. Genetic testing in isolated clefts consistently yielded normal results, reinforcing that prenatal genetic testing may be most valuable when additional anomalies or a strong family history are present. These findings underscore the need for multicenter studies to establish consistent and universal strategies for genetic testing and counseling in pregnancies complicated by orofacial clefts.

ACKNOWLEDGMENTS

During the preparation of this work, the authors used OpenAI's ChatGPT-4 to improve readability and language. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

AUTHOR CONTRIBUTIONS

HD, RO, TC, MMo: Study conception and design, data acquisition, analysis and interpretation, writing and critical review of the manuscript.

DFR, MHC, SG: Data acquisition, analysis and interpretation, critical review of the manuscript.

ACB, MMA, CPM: Critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

FUNDING SOURCES

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

REFERENCES

1. Farladansky-Gershnabel S, Gluska H, Halevi N, Kotser N, Sharon-Weiner M, Schreiber H, et al. Cleft lip and/or cleft palate: prenatal accuracy, postnatal course, and long-term outcomes. *Children*. 2022;9:1880.
2. Chmait R, Pretorius D, Moore T, Hull A, James G, Nelson T, et al. Prenatal detection of associated anomalies in fetuses diagnosed with cleft lip with or without cleft palate in utero. *Ultrasound Obstet Gynecol*. 2006;27:173-6.
3. Celik OY, Bucak M, Saglam E, Kahraman NC, Kaymak AO, Arat O, et al. Diagnostic performance of two ultrasound techniques for the detection of cleft palate without cleft lip: axial-transverse and equal sign. *Eur Rev Med Pharmacol Sci*. 2023;27:1971-9.
4. Basha M, Demeer B, Revencu N, Helaers R, Theys S, Bou Saba S, et al. Whole exome sequencing identifies mutations in 10% of patients with familial non-syndromic cleft lip and/or palate in genes mutated in well-known syndromes. *J Med Genet*. 2018;55:449-58.
5. Kini U. Genetics and orofacial clefts: a clinical perspective. *Br Dent J*. 2023;234:947-52.
6. Vallino-Napoli LD, Riley MM, Halliday JL. An epidemiologic study of orofacial clefts with other birth defects in Victoria, Australia. *Cleft Palate Craniofac J*. 2006;43:571-6.
7. Setó-Salvia N, Stanier P. Genetics of cleft lip and/or cleft palate: association with other common anomalies. *Eur J Med Genet*. 2014;57:381-93.
8. Beriaghi S, Myers SL, Jensen SA, Kaimal S, Chan CM, Schaefer GB. Cleft lip and palate: association with other congenital malformations. *J Clin Pediatr Dent*. 2009;33:207-10.
9. Ács M, Cavalcante BG, Bănărescu M, Wenning AS, Hegyi P, Szabó B, et al. Maternal factors increase risk of orofacial cleft: a meta-analysis. *Sci Rep*. 2024;14:28104.
10. Cheng X, Du F, Long X, Huang J. Genetic inheritance models of non-syndromic cleft lip with or without palate: from monogenic to polygenic. *Genes*. 2023;14:1859.
11. Divya K, Iyapparaja P, Raghavan A, Diwakar MP. Accuracy of prenatal ultrasound scans for screening cleft lip and palate: a systematic review. *J Med Ultrasound*. 2022;30:169-75.
12. Lee MS, Cho JY, Kim SY, Kim SH, Park JS, Jun JK. Value of sagittal color Doppler ultrasonography as a supplementary tool in the differential diagnosis of fetal cleft lip and palate. *Ultrasonography*. 2017;36:53-9.
13. Chaoui R, Orosz G, Heling KS, Sarut-Lopez A, Nicolaidis KH. Maxillary gap at 11-13 weeks' gestation: marker of cleft lip and palate. *Ultrasound Obstet Gynecol*. 2015;46:665-9.
14. Wu S, Han J, Zhen L, Ma Y, Li D, Liao C. Prospective ultrasound diagnosis of orofacial clefts in the first trimester. *Ultrasound Obstet Gynecol*. 2021;58:134-7.
15. Sepulveda W, Wong AE, Martinez-Ten P, Perez-Pedregosa J. Retronasal triangle: a sonographic landmark for the screening of cleft palate in the first trimester. *Ultrasound Obstet Gynecol*. 2010;35:7-13.
16. Lakshmy SR, Rose N, Masilamani P, Umapathy S, Ziyauulla T. Absent 'superimposed-line' sign: novel marker in early diagnosis of cleft of fetal secondary palate. *Ultrasound Obstet Gynecol*. 2020;56:906-15.
17. Lachmann R, Schilling U, Brückmann D, Weichert A, Brückmann A. Isolated cleft lip and palate: maxillary gap sign and palatino-maxillary diameter at 11-13 weeks. *Fetal Diagn Ther*. 2017;44:241-6.
18. Platt LD, Devore GR, Pretorius DH. Improving cleft palate/cleft lip antenatal diagnosis by 3-dimensional sonography: the "flipped face" view. *J Ultrasound Med*. 2006;25:1423-30.
19. Ramos GA, Ylagan MV, Romine LE, D'Agostini DA, Pretorius DH. Diagnostic evaluation of the fetal face using 3-dimensional ultrasound. *Ultrasound Q*. 2008;24:215-23.
20. Stanier P, Moore GE. Genetics of cleft lip and palate: syndromic genes contribute to the incidence of non-syndromic clefts. *Hum Mol Genet*. 2004;13:R73-81.
21. Beaty TH, Marazita ML, Leslie EJ. Genetic factors influencing risk to orofacial clefts: today's challenges and tomorrow's opportunities. *F1000Res*. 2016;5:2800.
22. Maarse W, Pistorius LR, Van Eeten WK, Breugem CC, Kon M, Van den Boogaard MJ, et al. Prenatal ultrasound screening for orofacial clefts. *Ultrasound Obstet Gynecol*. 2011;38:434-9.
23. Calzolari E, Pierini A, Astolfi G, Bianchi F, Neville AJ, Rivieri F. Associated anomalies in multi-malformed infants with cleft lip and palate: an epidemiologic study of nearly 6 million births in 23 EUROCAT registries. *Am J Med Genet A*. 2007;143a:528-37.
24. Monlleó IL, Barros AG, Fontes MI, Andrade AK, de M Brito G, Nascimento DL, et al. Diagnostic implications of associated defects in patients with typical orofacial clefts. *J Pediatr*. 2015;91:485-92.
25. Yuan Q, Blanton SH, Hecht JT. Association of ABCA4 and MAFB with non-syndromic cleft lip with or without cleft palate. *Am J Med Genet A*. 2011;155a:1469-71.
26. Zawislak A, Woźniak K, Agirre X, Gupta S, Kawala B, Znamirska-Bajowska A, et al. Association of ABCA4 gene polymorphisms with cleft lip with or without cleft palate in the Polish population. *Int J Environment Res Pub Health*. 2021;18:11483.
27. Sheppard SE, Quintero-Rivera F. Wiedemann-Steiner syndrome. In: Adam MP, Feldman J, Mirzaa GM, Pagon RA, Wallace SE, Amemiya A, editors. *GeneReviews*(®). Seattle: University of Washington, Seattle; 1993.
28. Veroniki AA, Cogo E, Rios P, Straus SE, Finkelstein Y, Kealey R, et al. Comparative safety of anti-epileptic drugs during pregnancy: a systematic review and network meta-analysis of congenital malformations and prenatal outcomes. *BMC Med*. 2017;15:95.
29. Babai A, Irving M. Orofacial clefts: genetics of cleft lip and palate. *Genes*. 2023;14:1603.

Research Burden in the Portuguese Residency Program: Cardiology's Unique Challenge

Exigência Científica no Internato Português: O Desafio Único da Cardiologia

Gonçalo FERRAZ-COSTA ^{1,2,3}, Vanda DEVESA NETO ^{3,4}, João PRESUME ^{3,5}, Diogo SANTOS-FERREIRA ^{3,6}, Pedro AZEVEDO ^{3,7}, José DURÃO ^{8,9}, Fernando MONTENEGRO SÁ ^{3,10}
Acta Med Port 2026 Jan;**39**(1):41-44 • <https://doi.org/10.20344/amp.23626>

ABSTRACT

This study analyses the research output expected for the final curricular evaluation of Portuguese medical residency programs, with particular focus on cardiology. All publicly available specialty-specific evaluation grids were reviewed in December 2024. Cardiology required 46 research items to attain maximum scoring, including research papers and congress abstracts stratified by journal quartile. This was the highest requirement among all specialties, compared to a median of 11 across all specialties. Uniquely, cardiology was the only specialty to quantitatively specify participation in research projects, clinical trials, and registries. In contrast, it scored below average in the most recent national residency satisfaction survey. However, no significant correlation was observed between the number of required research items and overall satisfaction. These findings suggest a potential misalignment between curricular evaluation criteria and the actual conditions of residency training. Reviewing these requirements may help create a more balanced and sustainable training environment.

Keywords: Biomedical Research; Cardiology/education; Curriculum; Internship and Residency; Portugal

RESUMO

Este estudo analisa os requisitos de produção científica definidos para a avaliação curricular final dos programas de internato médico em Portugal, com especial foco na Cardiologia. Todas as grelhas de avaliação específicas por especialidade, disponíveis publicamente, foram revistas em dezembro de 2024. A Cardiologia revelou a exigência mais elevada, requerendo um total de 46 itens de investigação para atingir a pontuação máxima — incluindo artigos científicos e resumos apresentados em congressos, estratificados de acordo com o quartil da revista. Em comparação, a mediana entre todas as especialidades foi de 11 itens. De forma singular, a Cardiologia foi a única especialidade a quantificar explicitamente a participação em projetos de investigação, ensaios clínicos e registos. Em contraste, apresentou uma classificação inferior à média no inquérito nacional mais recente de satisfação dos internos. Contudo, não se observou uma correlação significativa entre o número de itens de investigação exigidos e o nível global de satisfação. Estes resultados sugerem um possível desalinhamento entre os critérios de avaliação curricular e as condições reais de formação. A revisão destes requisitos poderá contribuir para um ambiente formativo mais equilibrado e sustentável.

Palavras-chave: Cardiologia/educação; Currículo; Internato e Residência; Investigação Biomédica; Portugal

Residency satisfaction and career decision-making

Specialist training is the cornerstone of postgraduate medical training in Portugal. For newly graduated doctors, selecting a residency program is a complex and multifactorial decision that significantly impacts their careers and personal lives.¹ Residency is also a period where doctors are particularly vulnerable to burnout due to factors such as young age, high workload, inadequate supervision, lack of autonomy, and the need for continued study outside of working hours.² In a 2016 national survey, cardiology was ranked second in overall satisfaction; however, in the most recent update, it experienced a significant decline and ranked second to last.³ Although not mandatory for com-

pleting the cardiology residency, the requirements for scientific production have become a *de facto* target, as they are perceived as necessary to improve career prospects and professional stability.

Therefore, our study aimed to compare the research work demands of the cardiology residency program with those of other specialties and to examine their relationship with overall residency satisfaction.

Curricular evaluation and research requirements

The final examination of the Portuguese residency program consists of three parts: theoretical, practical, and curricular assessments. The curricular evaluation varies

*: Co-first authors

1. Cardiology Department. Unidade Local de Saúde de Coimbra. Coimbra. Portugal.
2. Coimbra Institute for Clinical and Biomedical Research (iCBR). Coimbra. Portugal.
3. Conselho de Jovens Cardiologistas. Sociedade Portuguesa de Cardiologia. Lisbon. Portugal.
4. Cardiology Department. Unidade Local de Saúde de Viseu Dão-Lafões. Viseu. Portugal.
5. Cardiology Department. Unidade Local de Saúde Lisboa Ocidental. Lisbon. Portugal.
6. Cardiology Department. Centro Hospitalar Vila Nova de Gaia/Espinho. Porto. Portugal.
7. Cardiology Department. Unidade Local de Saúde do Algarve. Faro. Portugal.
8. Almada-Seixal Public Health Unit. Unidade Local de Saúde Almada-Seixal. Almada. Portugal.
9. Conselho Nacional do Médico Interno. Ordem dos Médicos. Lisbon. Portugal.
10. Unidade Local de Saúde de Matosinhos. Matosinhos. Portugal.

✉ Autor correspondente: Gonçalo Ferraz Costa. gfncoستا.93@gmail.com

Revisito por/Reviewed by: António Valentim Gonçalves , Luís Graça Santos 

Recebido/Received: 02/07/2025 - **Aceite/Accepted:** 15/09/2025 - **Publicado Online/Published Online:** 29/10/2025 - **Publicado/Published:** 02/01/2026

Copyright © Ordem dos Médicos 2026



between specialties, with scoring criteria set by each specialty's college under the Portuguese physician regulatory body, the Portuguese Medical Association. Research performance, which includes research papers, abstract presentations, and involvement in scientific projects/clinical trials, is part of the curricular assessment. Although the curriculum grid does not specify a minimum number of research items, it does set a maximum score for each category.

We systematically reviewed every publicly available Portuguese-certified medical specialty curriculum grid in December 2024, extracting the minimum number of research items required for maximum score in research performance. Subgroup analyses were performed based on research type, quality requirements, and miscellaneous categories.

In addition, we analyzed the association between the number of research outputs required for maximum scoring and each specialty's overall satisfaction score, as reported in the most recent national residency satisfaction survey.

Research demands across Portuguese specialties

Portugal has 48 certified medical specialties. Of these, 8 (16%) lacked formal curricular grids. Of the remaining specialties, 13 (31%) had no cap on the maximum score for publications or poster/oral presentations. Cardiology required a minimum of 46 scientific production items, includ-

ing six research papers as first author in 1st or 2nd quartile journals, 20 abstracts as first author published in 1st or 2nd quartile journals' supplements, and 20 abstracts published as first author in 3rd or 4th quartile journals' supplements. Across all specialties, the median number of required research items was 11 [8, 19.5], with cardiology being an outlier along with allergy and immunology (36) (Fig. 1).

Regarding quality, ten specialties (23.8%) had no specific journal requirements, 29 (69%) distinguished between indexed and non-indexed journals, and only two (4.8%) differentiated between journal quartiles (cardiology and plastic surgery).

Furthermore, cardiology required participation in two scientific projects, two clinical trials, and two national/international registries. While 26 specialties (61.9%) valued participation in scientific projects, the majority of these (78.5%) did not specify a minimum number required for full scoring. Only five specialties explicitly mentioned involvement in clinical trials in their grids, and only cardiology specifically required contributions to registries. Additionally, the cardiology grid was unique in requiring invited lectures at scientific meetings, teaching activities, and completion of a doctoral degree to achieve maximum scoring.

In the national residency satisfaction survey, cardiology scored lower than the average (3.69/5 vs 4.12/5), despite the lower response rate (16% vs 19%). Pearson's

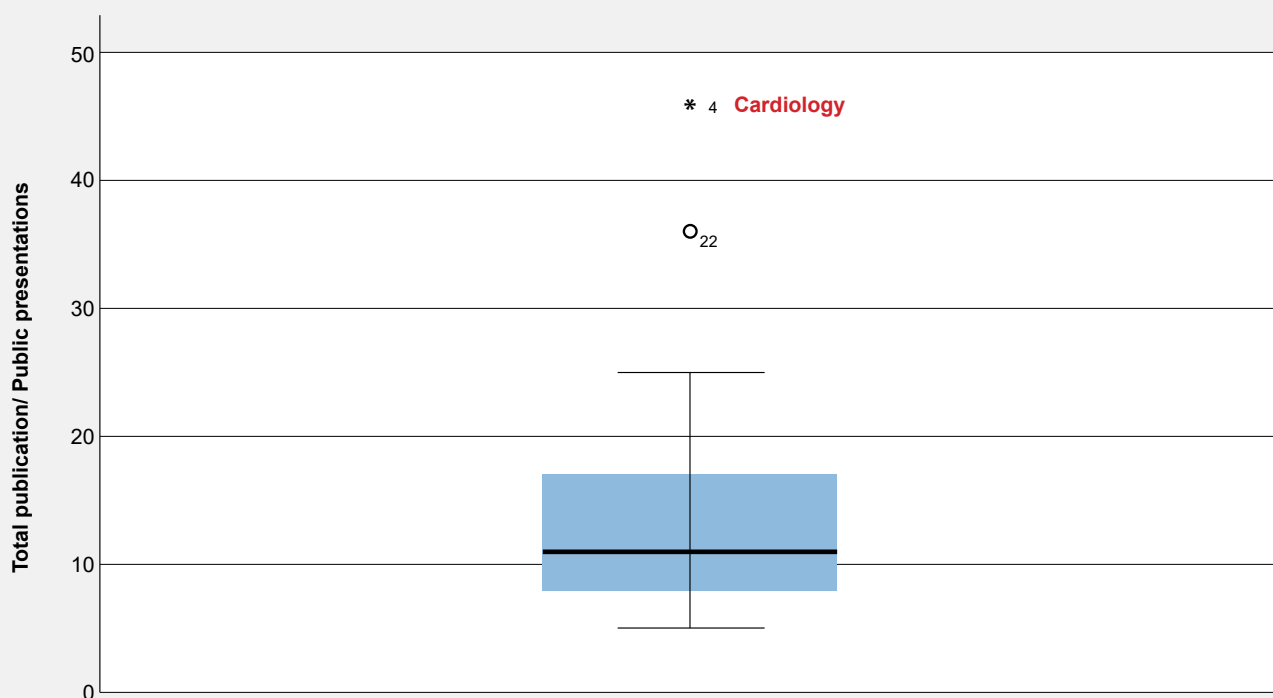


Figure 1 – Box plot showing the distribution of total publications/public presentations across all Portuguese certified specialties. The central line represents the median, with the box spanning the interquartile range (IQR). Whiskers extend to 1.5 times the IQR. Cardiology is an extreme outlier and Allergy and Immunology is an outlier.

correlation analysis revealed no significant relationship between the number of scientific production items and overall satisfaction ($r = 0.043$, $P = 0.823$).

Implications for cardiology training and resident well-being

Our study highlights the high research expectations placed on Portuguese cardiology residents compared to other specialties. Cardiology requires 46 high-quality research items for maximum score on curricular evaluation, far exceeding the median of 11 items across specialties, many of which do not impose quality restrictions.

The high research work demands during the cardiology residency can be compared to the concept of 'hard training' from the perceptual learning study of Garcia *et al.*⁴ In this study, harder tasks led to quicker, more intense improvements, while easier tasks resulted in slower, more gradual progress. Similarly, cardiology's stringent research work expectations push residents to rapidly develop advanced research skills. However, just as arduous training requires continuous effort, the high expectations in cardiology could challenge residents' ability to balance clinical and research responsibilities. Notably, the cardiology residency includes no dedicated research rotations, and most hospitals do not allow protected time for research.

Despite the heavy research burden, no significant correlation was found between the number of required research items and overall residency satisfaction. This suggests that factors such as clinical workload, mentorship, or work-life balance may also contribute to dissatisfaction among cardiology residents.² These elements, when combined with high research expectations, could amplify the risk of burnout. However, a limitation of our study is the lower response rate among cardiology residents (16% vs 19% for the general survey population). This reduced participation may have influenced the satisfaction scores, as the smaller sample size could underrepresent the broader experiences of cardiology residents. As a result, the data may not fully capture the diversity of opinions or the true extent of dissatisfaction within the specialty. Nevertheless, the decline in cardiology satisfaction coincided with the implementation of the new evaluation grid, and this is unlikely to be explained solely by participation bias. Thus, the findings should be interpreted with caution, particularly regarding the levels of dissatisfaction in cardiology compared to other specialties, while also highlighting the importance of encouraging broader participation in residency satisfaction surveys through stronger institutional endorsement, integration into training evaluation, or digital reminders.

Another relevant implication is the potential impact on specialty attractiveness. The significant emphasis on research work may discourage top-ranked medical appli-

cants from choosing cardiology, redirecting them towards specialties that place greater value on clinical practice. Furthermore, we can speculate that the diversion of time and energy from clinical training to research activities risks undermining the acquisition of essential technical skills, thus potentially compromising the future of cardiologists as healthcare providers.

Our analysis suggests that the cardiology residency in Portugal is an outlier among all specialties due to its uniquely high scientific requirements. Resident satisfaction has also declined in recent years, coinciding with the implementation of these demands, which raises concerns about the sustainability and long-term attractiveness of the specialty.

ACKNOWLEDGMENTS

The authors have declared that ChatGPT Open AI was used for the purpose of copyediting the manuscript. After using this tool, the content was reviewed and edited by the authors, who assume full responsibility for the content.

AUTHOR CONTRIBUTIONS

GFC, VDN: Conceptualization, data curation, original draft.

JP, DSF, PA, JD, FMS: Critical review of the manuscript. All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

CONFLICTS OF INTEREST

JD is the president of the Portuguese Council of Medical Residents of the Portuguese Medical Association.

FM received consulting fees from Medtronic, Abbott and Microport; received payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from Medifar and Azevedos; received payment for expert testimony from Novartis; received support for attending meetings or travel from Pfizer; has a leadership or fiduciary role in Sociedade Portuguesa de Cardiologia.

PA received payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from Daiichi-Sankyo, Boehringer Ingelheim and

Amarin; received support for attending meetings or travel from Amarin and Abbott.

All other authors have no conflicts of interest to declare.

FUNDING SOURCES

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

REFERENCES

1. Dyrbye LN, Burke SE, Hardeman RR, Herrin J, Wittlin NM, Yeazel M, et al. Association of clinical specialty with symptoms of burnout and career choice regret among US resident physicians. JAMA. 2018;320:1114-30.
2. Martins S, Bastos J, Mendonça C, Franco-Pego F, Durão J, Inácio R. Burnout among Portuguese residents: a case for change. Acta Med Port. 2024;37:682-3.
3. Bigotte Vieira M, Godinho P, Gaibino N, Dias R, Sousa A, Madanelo I, et al. Satisfação com o internato médico em Portugal. Acta Med Port. 2016;29:839-53.
4. Garcia A, Kuai SG, Kourtzi Z. Differences in the time course of learning for hard compared to easy training. Front Psychol. 2013;4:1-8.

Rethinking Morbidity and Mortality Meetings in Surgery

Repensando as Reuniões de Morbilidade e Mortalidade em Cirurgia

António Pedro GOMES ¹, Vitor NUNES ¹

Acta Med Port 2026 Jan;39(1):45-54 • <https://doi.org/10.20344/amp.23724>

ABSTRACT

Morbidity and mortality meetings were originally conceived as structured forums to improve surgical outcomes through reflective practice. Over time, they became institutionalized globally. However, in Portugal, no published evidence was found describing structured standards for morbidity and mortality meetings; available observations suggest that practices remain fragmented, unstandardized, and weakly integrated into clinical governance. The aim of this review to critically appraise the current model of morbidity and mortality meetings in Portuguese surgical departments and propose evidence-based reforms, drawing on successful international frameworks. This is a narrative review synthesizing historical developments, national regulations, and international models – such as the United Kingdom's National Confidential Enquiry into Patient Outcome and Death, the National Surgical Quality Improvement Program, and Australian and New Zealand Audit of Surgical Mortality. This work highlights gaps in the Portuguese context and proposes a multidimensional reform strategy. Despite legal references to morbidity and mortality in Portuguese regulations, there is no unified national guidance on case selection, meeting governance, or implementation of corrective actions. Cultural barriers such as blame avoidance and hierarchical dynamics limit psychological safety and learning. In contrast, international programs offer structured, audited, and data-driven approaches that promote accountability, transparency, and system-wide improvement. Based on these findings, the review recommends national guidelines, risk-adjusted benchmarking, multidisciplinary involvement, protected meeting time, and formal follow-up systems. Additional proposals include autopsy integration, shared morbidity and mortality across institutions, and public reporting. Morbidity and mortality meetings in Portugal must evolve from symbolic practices into powerful tools for patient safety, institutional accountability, and continuous learning. This requires regulatory leadership, cultural change, and structural reform aligned with international standards.

Keywords: Clinical Governance; Morbidity; Mortality; Patient Safety; Portugal; Quality Improvement; Specialties, Surgical/education; Surgery Department, Hospital/organization and administration; Surgical Procedures, Operative/education

RESUMO

As reuniões de morbimortalidade foram idealizadas como fóruns estruturados, sem culpabilização, para melhorar os resultados cirúrgicos através da reflexão. No entanto, em Portugal, não foi encontrada evidência publicada que descreva normas estruturadas para as reuniões de morbimortalidade; as observações disponíveis sugerem que as práticas permanecem fragmentadas, não normalizadas e pouco integradas na gestão clínica. O objetivo desta revisão é analisar criticamente o modelo atual de reuniões de morbimortalidade nos serviços cirúrgicos portugueses e propor reformas fundamentadas na evidência, inspiradas em modelos internacionais eficazes. Esta revisão narrativa integra evolução histórica, normas nacionais e experiências internacionais como o *National Confidential Enquiry into Patient Outcome and Death* (Reino Unido), o *National Surgical Quality Improvement Program* (Estados Unidos da América) e o *Australian and New Zealand Audit of Surgical Mortality*, identificando falhas e propondo uma estratégia multidimensional de reforma. Apesar de existirem referências a morbimortalidade nas regulamentações portuguesas, não existe um guia nacional sobre seleção de casos, condução das reuniões ou implementação de medidas corretivas. Barreiras culturais como o medo de culpabilização e dinâmicas hierárquicas dificultam o ambiente de segurança psicológica. Em contraste, os modelos internacionais oferecem abordagens estruturadas, auditadas e orientadas por dados. Recomenda-se a criação de diretrizes nacionais, *benchmarking* ajustado ao risco, participação multidisciplinar, tempo protegido, e sistemas formais de seguimento. Propõem-se ainda a integração do resultado de autópsias, partilha interinstitucional e publicação de resultados. As reuniões de morbimortalidade em Portugal devem evoluir de rituais simbólicos para instrumentos efetivos de segurança do doente e melhoria contínua, exigindo liderança regulatória, mudança cultural e reformas estruturais alinhadas com os padrões internacionais.

Palavras-chave: Especialidade Cirúrgicas/educação; Governação Clínica; Melhoria da Qualidade; Morbilidade; Mortalidade; Portugal; Procedimentos Cirúrgicos Operatórios/educação; Segurança do Doente; Serviço de Cirurgia/organização e administração

INTRODUCTION

Morbidity and mortality (M&M) meetings, once an innovative tool for surgical education, have become stagnant in many healthcare settings.¹⁻³ Originally conceived in the early 20th century to support reflective learning and improve outcomes, they offered clinicians a space to discuss complications and deaths constructively – not to assign blame, but to identify patterns and improve care. Over time, they became institutionalized globally, particularly in surgery where decision-making stakes are high.³⁻⁸

Today, M&M meetings are endorsed by professional bodies and embedded in accreditation frameworks.^{2-7,9} Yet, in practice, they often fall short – more ritual than reflection, more symbolic than substantive. The lack of oversight and integration into broader quality systems, especially in countries like Portugal, has widened the gap between their intended and actual impact.¹⁰⁻¹²

Our objective was to assess the current state of M&M meetings in Portuguese surgical departments and compare them with international models.

1. Surgery Department. Hospital Fernando Fonseca. Amadora. Portugal.

✉ **Autor correspondente:** António Pedro Gomes. antonio.p.gomes@ulsasi.min-saude.pt

Revisão por/Reviewed by: Rita Costa 

Recebido/Received: 24/07/2025 - **Aceite/Accepted:** 29/09/2025 - **Publicado Online/Published Online:** 12/11/2025 - **Publicado/Published:** 02/01/2026

Copyright © Ordem dos Médicos 2026



METHODS

As a narrative review, this work synthesized historical developments, national regulations, and international frameworks. Searches were conducted in MEDLINE/PubMed, Embase, and Google Scholar, complemented by targeted searches of the grey literature, including institutional documents, regulatory publications, and congress proceedings. Particular attention was given to international programs such as the United Kingdom (UK)'s National Confidential Enquiry into Patient Outcome and Death (NCEPOD), the United States of America (USA)'s National Surgical Quality Improvement Program (NSQIP), and the Australian and New Zealand Audit of Surgical Mortality (ANZASM), which were analyzed to provide comparative perspectives.

THE CURRENT MODEL IN PORTUGAL: GAPS IN STRUCTURE, CULTURE, AND IMPACT

Portugal is a compelling case study. Morbidity and mortality meetings are a common feature of surgical practice in Portugal, but their structure and effectiveness vary widely across institutions. While legal instruments such as *Portaria* 186/2024/1,¹³ and the *Declaração da Terceira*,¹⁴ as well as and professional bodies – such as the College of General Surgery of the Portuguese Medical Association,¹⁵ – mandate regular clinical meetings including bimonthly or quarterly M&M reviews (Table 1), there is no national standard guid-

ing how these meetings should be conducted. The Portuguese National Health Plan 2021 - 2030¹⁶ sets public health priorities but does not specifically address surgical morbidity and mortality. Although guidelines from the Directorate-General of Health (DGS)—such as *Norma* 002/2013¹⁷ (Table 1)—promote internal audits and patient safety, and the World Health Organization¹⁸ (WHO) recommendations have been incorporated into national policy, there remains no unified operational framework for conducting morbidity and mortality (M&M) meetings. As a result, implementation is inconsistent and unmonitored, and there is no mechanism to ensure follow-up of recommendations.

This lack of standardization fosters significant variability, and the absence of national data limits understanding of the true scope of the problem. Cultural barriers – hierarchical structures, fear of blame, and limited psychological safety – further impede open and constructive discussion. By contrast, international models from the UK, USA, Canada, and Australia have transformed M&M meetings into strategic tools for quality improvement, grounded in data, accountability, and system-wide learning.³⁻⁹

THE EVOLUTION OF SURGICAL MORBIDITY AND MORTALITY MEETINGS: A CENTURY OF TENSION AND TRANSFORMATION

Surgical M&M meetings originated in the early 20th

Table 1 – Current regulatory and policy framework for surgical M&M meetings in Portugal

Source	Document / Policy	Content
College of the Specialty of General Surgery; Portuguese Medical Association ^{14,15}	<i>Declaração da Terceira, 2022</i> - Point 4.1.2, Annex 1 - Point 2.2 of Article 2 nd and point 1.6 of Article 6 Annex 2 - Point 1, Chapter III	“(…) morbidity and mortality analysis to be conducted on a bimonthly or quarterly basis; critical review of the caseload managed by the Service's Teams/Functional Units (…)”
	<i>Criteria for the Assessment of Training Suitability and Training Capacity of General Surgery Services</i> - Point 2.2 Article 3 rd - Point 1.2 Article 6 th	
<i>Portaria</i> 186/2024/1 (August 14 th 2024) ¹³	“Approves the updated curriculum for specialty training in General Surgery”	“Presentation of (…) and analysis of morbidity and mortality during the clinical meetings of (…).”
DGS <i>Norma</i> 002/2013 ¹⁶	Safe Surgery – Objective 10	“Hospitals and public health systems shall establish routine surveillance of surgical capacity, volume, and outcomes.”
National Health Plan (PNS 2021–2030) ¹⁷	<i>Norma</i> 002/2013 recommends internal audits and analysis of adverse surgical events	Recommends audits and analysis of adverse surgical events, aligning with the aims of M&M meetings
WHO Surgical Safety Guidelines (e.g., JCI, ACSA standards) ¹⁸	WHO Surgical Safety Guidelines (adopted in national regulations)	Some hospitals implement M&M meetings as part of broader quality and safety programs

LIMITATIONS

No detailed operational standards provided (e.g., case selection, presentation format, documentation, follow-up, or moderation guidelines)

century as surgery shifted toward a data-driven science. Ernest Codman's 1914 "End Result System" introduced the principles of outcome tracking, transparency, and continuous improvement.¹⁹⁻²² Despite institutional resistance and his eventual ostracism, Codman's legacy laid the foundation for modern peer review and system accountability in surgery.

In the US, formal standardization began in 1950 with the Residency Review Committee for Surgery, and by 1983, the Accreditation Council for Graduate Medical Education integrated M&M into residency programs.²³⁻²⁵ Parallel reforms arose in the Veterans Affairs system, culminating in the National Surgical Quality Improvement Program (NSQIP), which used risk-adjusted outcomes to drive surgical quality. NSQIP's success led to its civilian expansion by the American College of Surgeons (ACS) in 2004.⁴ The ACS-NSQIP program has strengthened M&M processes through standardized, data-driven peer review. Participating hospitals collect risk-adjusted surgical outcome data and benchmark it nationally to identify trends, improve care, and monitor interventions. The ACS-NSQIP criteria increased complication detection in M&M meetings from 15% to 81% and improved mortality identification from 33% to 100%. Long-term NSQIP participation is associated with a 25% reduction in postoperative complications and declines in surgical mortality.^{4,26-30}

The "To Err is Human" report from 1999 reframed patient harm as systemic rather than individual, advancing root cause analysis and the concept of a 'just culture'.^{31,32} These ideas fundamentally reshaped M&M as a learning opportunity embedded within broader quality systems. Globally, M&M practices evolved in tandem.

In the UK, in 1987, the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) introduced anonymized case reviews, inspiring the National Health Service's Learning from Deaths programme.^{9,33-35} The NCEPOD uses random case sampling and blinded peer review to assess care quality, producing anonymized reports that identify systemic failures and guide national recommendations. Complementing the Learning from Deaths policy requires all National Health Service hospitals to conduct structured reviews of in-hospital deaths using standardized formats. Significant findings must be escalated to medical examiners, discussed in M&M meetings, and reported publicly. Hospitals must demonstrate improvements via quarterly reporting, and visible implementation of changes.^{8,9,12,34-36}

The Canadian Medical Protective Association (CMPA) shifted focus to cognitive error and system learning.⁵ Australia and New Zealand launched the Australian and New Zealand Audit of Surgical Mortality (ANZASM) in 2005, requiring peer-reviewed audits of all surgical deaths.⁷ The ANZASM is a mandatory, national peer-review program for all

surgical deaths in public hospitals. Since its full implementation in 2010, it has captured nearly 100% of eligible deaths and helped reduce surgical mortality by 30% in Western Australia and by 15% nationwide between 2009 and 2013. The ANZASM's structured feedback process identifies modifiable care issues – such as delayed intervention or inadequate rescue after complications – informing both clinical education and system change. It has enabled publication of audits across common surgeries (e.g., cholecystectomy, pancreatic resections, liver resections), highlighting recurrent risks and guiding safer practice.³⁷⁻⁴⁸

All the programs mentioned above share core principles: standardized data collection, protected peer review, and integration with governance and education. Such national initiatives complement M&M meetings by enabling large-scale audits, benchmarking, and policy development. While hospital-level data are confidential, national summaries from ANZASM, NCEPOD, and ACS-NSQIP are publicly available, balancing transparency with internal learning.

Recent years have seen growing international efforts to structure surgical M&M practices, particularly in South America and Africa. For example, Ecuador launched a WHO-supported National Surgical, Obstetric, and Anaesthesia Plan (NSOAP) in 2023, followed by Brazil, Colombia, and Peru. However, the scope and pace of implementation vary across countries.⁴⁹⁻⁵¹ In Africa, countries like Tanzania, Rwanda, and Ethiopia have adopted NSOAPs that include M&M processes. Initiatives like SURG-Africa and COST-Africa show how structured M&M and mentorship can improve safety, even in resource-limited settings.^{52,53}

Figure 1 provides a schematic overview of the key historical milestones in the evolution of morbidity and mortality (M&M) discussions.

KEY MOMENTS IN M&M MEETINGS REQUIRING STANDARDIZATION

International quality programs such as NSQIP, NCEPOD, and ANZASM promote M&M meetings as vital tools for safety, accountability, and learning. However, they rarely define operational standards in detail, leaving institutions to develop their own protocols, aligned with national frameworks.^{6,54-61}

Case selection

Case selection is critical for the educational and quality assurance goals of M&M meetings. Key questions include: Which cases merit discussion, who selects them, and how can omissions be avoided? A core debate concerns whether to include all complications or only those considered 'unexpected'.⁵⁵ This term is subjective and prone to bias, and therefore a clearer clinical definition should consider pre-operative risk, clinical trajectory, and whether the outcome

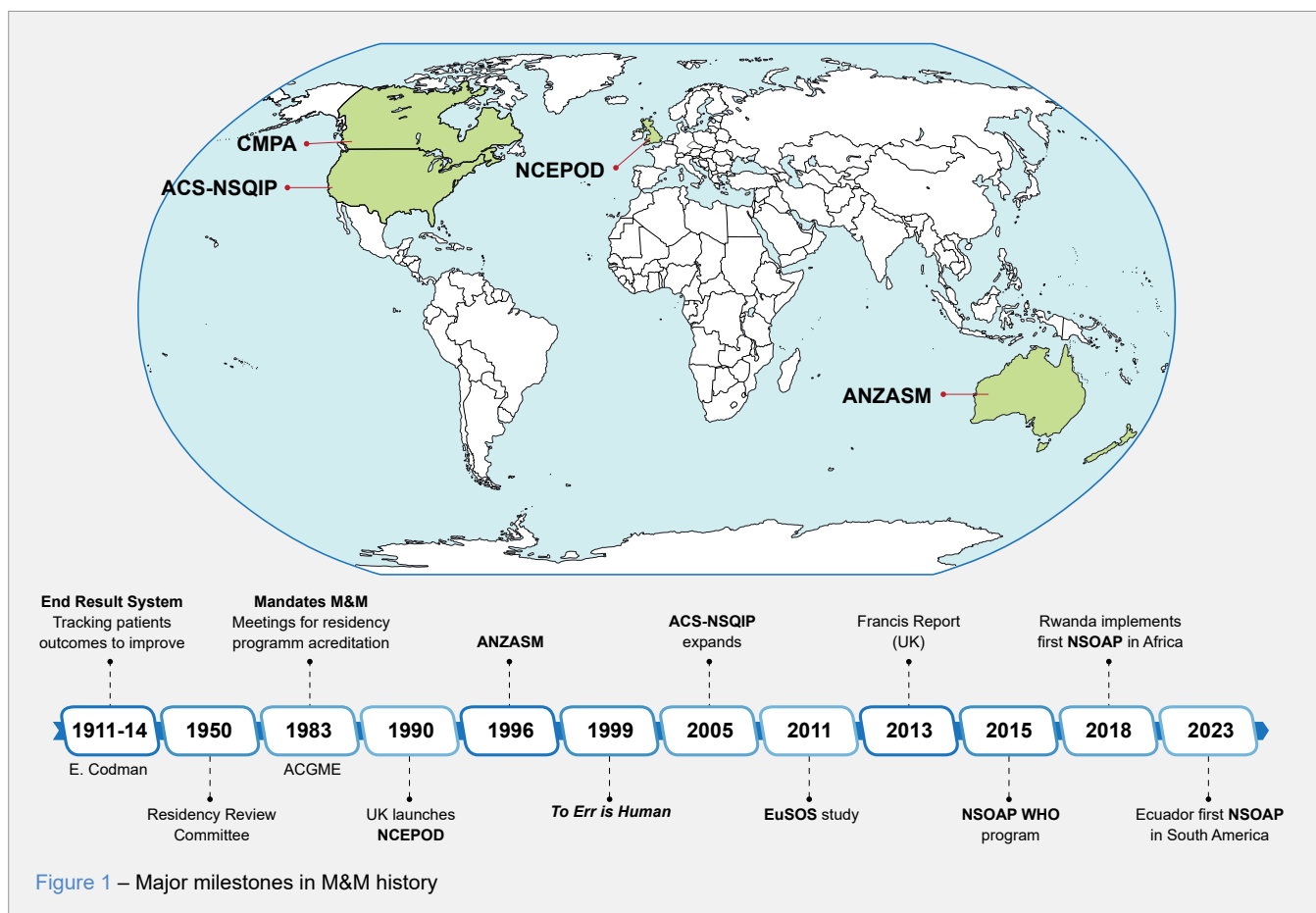


Figure 1 – Major milestones in M&M history

aligned with prior expectations. For example, a death may be considered 'expected' if it occurred after high-risk surgery in a frail or severely comorbid patient and was discussed in advance with the patient and team.^{54,55,57} In contrast, 'unexpected deaths' occur when mortality was not anticipated – such as a healthy patient dying from unrecognized sepsis after elective cholecystectomy, or a routine colectomy ending in fatal anesthetic complications. These warrant thorough review, as they may indicate diagnostic errors, management failures, or systemic issues. The use of risk prediction tools such as the American Society of Anesthesiologists Score,⁶² Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM),^{63,64} or NSQIP⁶⁵ can help define risk more objectively. Some health services, like the ones used in Victoria and Canberra offer already structured systems to classify deaths as 'expected', 'unexpected', or 'opportunities for improvement'.⁵⁵ This facilitates consistent referral and prioritization for in-depth review.

Criteria for M&M case submission (Table 2)

In answering "Which patients should be referred to M&M

meetings?", several case types stand out:

- **Deaths related to healthcare interventions**, especially unexpected ones or those involving potential medical error. In medico-legal systems, such cases often require statutory reporting.^{56,66}
- **Adverse events and complications**, such as unplanned returns to the operating theatre or ICU, postoperative bleeding, hospital-acquired infections, or unexpected readmissions (e.g., within 30 days of discharge or 72 hours from the emergency department).
- **Near misses and 'close calls'**, especially if they reveal recurring system vulnerabilities.
- **High-risk but successful cases** with educational value, or those exposing latent safety issues.
- **Cases flagged by incident reporting systems** (e.g., Riskman, Victorian Health Incident Management System - VHIMS) or brought forward by patient/family feedback.
- **Breaches of care standards**, such as failure to implement sepsis protocols or thromboembolism prophylaxis.

Table 2 – Summary of recommended criteria for submission to M&M meeting

Category	Examples / Indicators	Justification / Purpose
Unexpected deaths	Mortality after low-risk elective surgery. Unanticipated deterioration post-discharge.	May signal errors in diagnosis, judgement, or system-level failures
Expected deaths with learning potential	High-risk surgery in frail patients. Deaths aligned with known prognosis.	Useful for reflecting on decision-making, communication, and end-of-life planning
Major adverse events / complications	Unplanned return to OR or ICU. Postoperative haemorrhage or sepsis	Identifies preventable harm, delays in recognition, or rescue failures
Readmissions / escalations of care	Readmission within 30 days. Unplanned ED revisits within 72 hours.	Suggests potential gaps in discharge planning or early detection of complications
Cases from incident reporting systems	Cases flagged in RiskMan, VHIMS, ... Internal alerts or sentinel events.	Aligns clinical governance with incident management systems
Near misses/close calls	Events that nearly caused harm but were averted. Pattern of recurring vulnerabilities.	Highlights system resilience and opportunities for proactive correction
Breach of standard of care/KPIs	Failure to administer prophylaxis. Missed sepsis bundle application.	Supports accountability and audit of care delivery standards
Patient or family feedback	Serious complaints or reported dissatisfaction. Compliments after complex care.	Encourages responsiveness to patient experience and identifies blind spots
Positive deviance/high-risk successes	Excellent outcomes in high-risk settings. Innovative or multidisciplinary approaches.	Promotes learning from success, not just failure
Cases with system-wide learning potential	Issues crossing specialties (handover, coordination, resource delays).	Supports broader institutional learning and interdepartmental improvement

OR: operating room; ICU: intensive care unit; ED: emergency department; VHIMS: Victorian Health Incident Management System; KPIs: key performance indicators.

These categories support education and quality assurance. Institutions should tailor criteria based on resources, patient volume, and time constraints – ensuring regular meetings and fixed agendas.

Meeting governance

Creating a psychologically safe environment is the cornerstone of effective M&M meetings. Participants must feel confident that the primary objective is learning and improvement, not judgment or blame. A no-blame culture, when authentically implemented, encourages open disclosure, constructive reflection, and collaborative problem-solving. Institutions should explicitly state that M&M meetings are educational spaces, not forums for disciplinary action. Physical and procedural elements also matter: meetings should be conducted in confidential settings, free from clinical interruptions, and ideally attended by a multidisciplinary audience, including nursing, anesthesia, and quality officers.

Cultivating this environment requires visible leadership support, institutional policies with code of conduct, and ongoing training. Without it, even the best-case selection process risks becoming performative rather than transformative.

For M&M meetings to be effective and sustainable, well-defined governance and clear assignment of roles are crucial.

Patient selection should be coordinated by the clinical governance lead or quality officers, ideally in collaboration

with surgical, anesthetic, and nursing staff. Cases are typically presented by the involved clinician or trainee, following a structured format such as Situation - Background Assessment - Recommendation (SBAR)^{56,58,67} or a root cause analysis template.⁵⁶ However, in some settings, an uninvolved presenter may be preferable to reduce potential bias.

A senior, neutral moderator should chair the meeting to ensure psychological safety and constructive discussion. Administrative staff or quality officers must document discussion points and action items are formally documented.

Regular audits of the M&M process by clinical governance bodies are necessary to maintain standards.

Importantly, junior doctors should actively engage in M&M meetings, which should be an integral part of their training.

Ultimately, departmental leadership must ensure the institutionalization of the process, its periodicity, and the allocation of time, space, and resources. They also serve as accountability anchors and should reinforce the no-blame culture.

Meeting agenda

A structured and pre-circulated agenda is fundamental to ensuring that M&M meetings are focused, time-efficient, and purposeful. The agenda should be disseminated in advance and include the list of cases to be discussed, names of presenters, and any specific learning objectives or themes (e.g., communication breakdown, delays in

diagnosis, procedural error). The use of a standardized agenda template helps reinforce consistency across meetings and ensures time is allocated for discussion, recommendations, and follow-up of previous action points. The effectiveness of M&M meetings depends not only on their content but also on their timing and regularity. Irregular scheduling or skipped sessions can undermine their impact, while excessive delay between the adverse event and the meeting may reduce the relevance and clarity of the discussion.

Case presentation format

Presentations should be concise, factual, and objective, following a standardized format to facilitate clarity and focus. Common structures include SBAR or root cause analysis templates, such as the London Protocol or the Safer Care Victoria Systems-Focused Tool.⁵⁵ Ideally, the case should be presented by someone directly involved in care, supported by the responsible consultant or moderator. However, for sensitive or controversial cases, it may be advisable to assign presentation and analysis to an independent party to preserve neutrality and support psychological safety. The use of standardized templates reinforces consistency across meetings.

Case discussion and documentation

Root cause analysis should form the backbone of discussions, moving beyond superficial descriptions of error to understand contributing factors at system level (e.g., human factors, communication, environment, policy gaps).

Other models are also incorporated in different protocols worldwide like the Fishbone diagrams (Ishikawa) and the Swiss Cheese model to map system failures.⁶⁸ In cases of unexpected postoperative death, clinical autopsy remains a critical yet underutilized tool. Autopsy findings can help improve diagnostic accuracy, surgical decision-making, and perioperative management. In this context, clinical autopsy should be viewed not as an exception but as an essential tool for continuous learning and quality improvement.⁶⁹⁻⁷¹

Documentation is essential for accountability and follow-up. Each meeting should record the case details, findings, actions agreed upon, and attendance, ideally using standard templates.

Follow-up and dissemination

One of the most common failings of M&M meetings is the absence of effective follow-up. Each case must generate specific, measurable corrective actions with designated responsible individuals and deadlines. The Specific, Measurable, Achievable, Relevant, Time-bound (SMART) framework is frequently used to guide this process.

Documentation and registries

Formal documentation of cases reviewed, key findings, actions agreed, and attendance is critical for accountability and audit. A protected record of learnings and recommendation tracking should be maintained and periodically reported to governance structures. This documentation must balance transparency with legal and privacy obligations. Where possible, use standardized templates, and ensure data are regularly analyzed to identify recurrent themes or system vulnerabilities.

Lessons learned should be shared beyond the meeting itself – through written summaries, internal training sessions, or quality updates. To support open discussion, cases may be anonymized or reviewed in a blinded format when necessary. These practices are vital to cultivating a culture of honesty, accountability, and continuous learning, and should be explicitly reflected in the institution's code of conduct.

Confidentiality and legal protection

Fear of legal consequences or professional blame may inhibit open discussion. Institutions must ensure legal protection for M&M discussions where applicable and establish clear policies on confidentiality. Where possible, cases should be anonymized or reviewed in a blinded format to preserve psychological safety while maintaining transparency. These measures are vital to fostering a culture of honesty, accountability, and learning. The code of conduct should include these issues.

National guidelines and legal framework

To ensure the sustainability, equity, and institutional value of M&M practices, national health authorities should integrate M&M meetings into clinical governance frameworks. The development of national guidelines would support consistency across institutions, promote adherence to best practices, and facilitate external benchmarking.

Moreover, M&M meetings should be incorporated into hospital accreditation and quality assurance programs. Regulatory bodies should mandate the submission of anonymized summary reports and the implementation of regular audits to evaluate compliance, effectiveness, and impact. Transparent reporting and feedback loops between institutions and national oversight entities would enable continuous improvement and knowledge dissemination across the health system.

Importantly, the results of M&M processes should be made publicly available in a suitable and anonymized format. This transparency is essential to support informed patient choice and truly informed consent. Without access to such information, patients may be denied a critical component of decision-making.

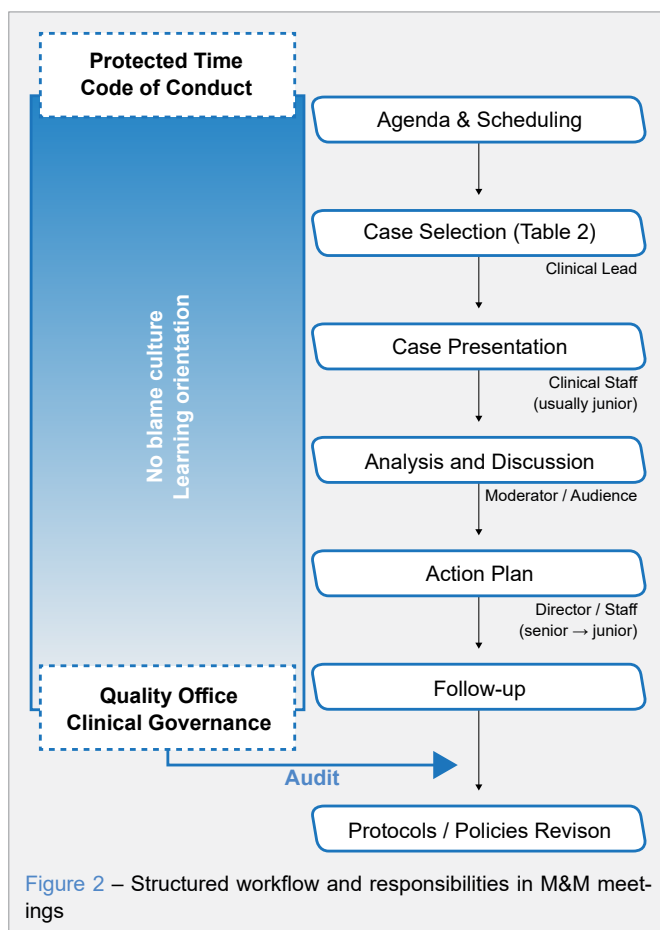


Figure 2 – Structured workflow and responsibilities in M&M meetings

Figure 2 summarizes the workflow and assigned responsibilities within morbidity and mortality (M&M) meetings, as outlined by the referenced international models.

FROM RITUAL TO REFORM: WHAT SHOULD CHANGE IN PORTUGAL?

Morbidity and mortality (M&M) meetings have long been a cornerstone of surgical practice, yet they remain underutilized in Portugal. Despite their potential as tools for institutional learning, current M&M practices are still treated more as rituals than as meaningful mechanisms for change.

To transform M&M meetings into effective instruments of quality assurance and safety, Portugal must implement structural, procedural, and cultural changes. Based on international experience and the gaps identified in the national context, the following key priorities are proposed:

- 1. National guidelines and central leadership.** Portugal must develop national guidelines that clearly define the operational standards of M&M meetings. These guidelines should be developed under the leadership of the DGS, in collaboration with the Portuguese Medical Association, surgical societies, and hospital governance

bodies. Central leadership is essential to ensure alignment, accountability, and the dissemination of best practices across institutions.

- 2. Definition of standardized criteria for case selection and discussion.** There must be a consistent, nationally agreed set of criteria for selecting cases for M&M meetings. Standardization will reduce variability, improve fairness, and ensure meaningful analysis. Another major challenge is the lack of risk-adjusted benchmarking between institutions. Hospitals performing complex or high-risk surgeries – such as transplant, advanced oncologic resections, or trauma – naturally report higher complication and mortality rates. National guidelines should provide clear direction on how M&M metrics are to be standardized for inter-hospital benchmarking.
- 3. Protected time and multidisciplinary involvement.** Morbidity and mortality meetings should be held at regular intervals in protected time slots, free from competing clinical duties. Attendance should be mandatory and multidisciplinary, including surgeons, residents, anesthesiologists, intensive care teams, nursing staff, and risk managers. This ensures a comprehensive view of events and fosters a culture of shared responsibility.
- 4. Structured presentation, analysis, and documentation.** Each institution should have their own templates based on national guidelines. Analysis should employ structured methods (e.g., root cause analysis, fishbone diagrams, Swiss cheese model) to identify system-level failures. All findings and actions must be documented in a standard format and stored in an internal registry.
- 5. On specialization and intra-hospital M&M silos.** In high-volume tertiary centers, subspecialization within surgical departments – such as hepatobiliary, colorectal, or endocrine surgery – has led to the tendency for each subspecialized team to review only their own cases. While this promotes clinical depth and peer familiarity, it may also reduce interdisciplinary learning, limit external critique, and foster insular thinking. Reflection is needed on the balance between focused expertise and broader institutional learning. Cross-subspecialty review of selected cases with systemic implications should be encouraged.
- 6. Clinical autopsies.** Autopsy findings should be shared with the M&M review team as part of the formal case analysis. The rate of autopsy requests in eligible cases should be monitored as a quality indicator. Institutions should aim for a target rate (e.g., $\geq 50\%$) of autopsies in unexpected surgical deaths where no clear cause is established.
- 7. Governance, oversight, and follow-up.** Hospitals should incorporate M&M reviews into their clinical governance structures. Designated committees must be

responsible for ensuring follow-up of corrective actions, auditing compliance, and reporting trends. These processes should be subject to periodic external review as part of hospital accreditation or performance evaluation.

8. **Publicly available results and transparency.** Anonymized, aggregated data from M&M meetings should be published in institutional or national reports. This would support transparency, foster public trust, and empower patients to make informed decisions. Moreover, it would provide critical insights for benchmarking and policy development.
9. **Educational integration and culture of learning.** The meetings must be integrated into residency training programs and continuing medical education. Emphasis should be placed on psychological safety, open dialogue, and system thinking. Institutions should promote a 'no blame, no shame' culture that encourages honest reflection and shared learning. Furthermore, the potential for cross-institutional learning remains underutilized. Shared M&M meetings between hospitals could promote benchmarking, expose blind spots, and disseminate innovations in clinical practice and governance. Such initiatives would enhance transparency as well as help harmonize practices across different care settings, especially between high-volume tertiary centers and smaller district hospitals. However, their implementation requires careful consideration of practical and ethical challenges. Confidentiality remains a central concern, particularly when discussing identifiable complications or adverse events. In addition, cross-hospital M&M integration depends on interoperable information technology, standardized documentation systems, and sufficient human resources to coordinate scheduling, moderation, and follow-up.

CONCLUSION

International experience demonstrates that M&M meetings can become powerful drivers of institutional learning – provided they are grounded in clear criteria, protected spaces for open dialogue, structured analysis, and robust documentation. Portugal now stands at a decisive crossroads: either continue to rely on outdated formats of limited impact, or evolve toward transparent, auditable, and genuinely educational systems. Such reform is not merely technical; it requires cultural and institutional commitment, leadership, and regulatory support. Creating psychologically safe environments, cultivating a 'no blame' ethos, and embedding M&M meetings within both postgraduate training and continuing professional development represent essential conditions for meaningful change. A key limitation of this review is the lack of real-world data from Portugal. Despite targeted searches the only documented analytical approach is a departmental

report presented at the Sociedade Portuguesa de Cirurgia's congress in 2014, which analyzed annual M&M outcomes for 2012 using locally defined methods.⁷² While this initiative was publicly presented and accessible for peer and patient scrutiny, it was not standardized at the national level and must also be interpreted with caution as a self-citation.

No additional institutional reports or published accounts of M&M practices were identified, underscoring the urgent need for systematic documentation and analysis of current approaches. Investigating how hospitals structure these meetings, and whether local guidelines or formal records exist, must therefore be a priority for future work. At the same time, broader questions remain unresolved and demand multidisciplinary reflection. Where does the threshold lie between a complication that should inform institutional learning and an event that warrants reporting as a medical error or malpractice? To what extent should patients and families have access to the conclusions drawn in these meetings? These are not purely medical dilemmas: they require input from legal and bioethical experts to ensure that M&M practices remain aligned with evolving human, ethical, and societal values.

By adopting these measures, Portugal can align its M&M practices with international standards – transforming them from symbolic rituals into pillars of patient safety, institutional accountability, and surgical quality. This review underscores the urgent need to reimagine M&M meetings in Portugal, shifting from fragmented and informal practices to structured, accountable, and learning-driven systems.

ACKNOWLEDGEMENTS

The authors thank Bruna Costa, from Fundação Champalimaud, for her valuable assistance in reviewing the manuscript.

The authors declare that no generative artificial intelligence tools were used to create or analyse the scientific content of this manuscript; AI-based tools were employed solely to improve English grammar and clarity.

AUTHOR CONTRIBUTIONS

All authors contributed equally to this manuscript and approved the final version to be published.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

FUNDING SOURCES

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

REFERENCES

1. Song YK. Rituals in medicine: the morbidity and mortality conference. *J Ritual Stud.* 2018;32:1-10.
2. Bernstein J. Not the last word: morbidity and mortality conference: theater of education. *Clin Orthop Relat Res.* 2016;474:882-6.
3. Nussenbaum B, Chole RA. Rethinking morbidity and mortality conference. *Otolaryngol Clin North Am.* 2019;52:47-53.
4. American College of Surgeons. ACS-NSQIP Quality programs history. [cited 2025 May 21]. Available from: <https://www.facs.org/quality-programs/data-and-registries/acs-nsqip/history/>.
5. Canadian Medical Protective Association. Quality improvement and accountability reviews: learning from patient safety incidents and near misses. 2024. [cited 2025 May 21]. Available from: <https://www.cmpa-acpm.ca/en/advice-publications/handbooks/quality-improvement-and-accountability-reviews-learning-from-patient-safety-incidents-and-near-misses>.
6. The Royal College of Surgeons of England. Standards & Guidance. [cited 2025 May 21]. Available from: <http://www.rcseng.ac.uk/standardsandguidance>.
7. Royal Australasian College of Surgeons. More About ANZASM. [cited 2025 May 21]. Available from: <https://www.surgeons.org/research-audit/surgical-mortality-audits/more-about-anzasm>.
8. National Confidential Enquiry into Patient Outcome and Death. Home. [cited 2025 May 21]. Available from: <https://www.ncepod.org.uk/index.html>.
9. Nixon SJ. NCEPOD: revisiting perioperative mortality. *BMJ.* 1992;304:1128-9.
10. Biddle C, Oaster TR. Investigating the nature of the morbidity and mortality conference. *Acad Med.* 1990;65:420.
11. Pierluissi E, Fischer MA, Campbell AR, Landefeld CS. Discussion of medical errors in morbidity and mortality conferences. *JAMA.* 2003;290:2838-42.
12. Higginson J, Walters R, Fulop N. Mortality and morbidity meetings: an untapped resource for improving the governance of patient safety? *BMJ Qual Saf.* 2012;21:576-85.
13. Portugal. Portaria n.º 186/2024/1. Diário da República, I Série, n.º 157 (2024/08/14).
14. Ordem dos Médicos. Colégio de cirurgia geral, critérios de avaliação de idoneidade formativa e capacidade formativa aos serviços de cirurgia geral. 2023. [cited 2025 May 27]. Available from: <https://ordemdosmedicos.pt/files/pdfs/fnYB-CIF-Cirurgia-Geral-2023.04.05.pdf>.
15. Direção do Colégio da Especialidade de Cirurgia Geral da Ordem dos Médicos. A cirurgia e o cirurgião do sec XXI. contributo da direção do colégio de cirurgia geral da ordem dos médicos para as reformas na saúde em Portugal * "declaração da terceira". 2022. [cited 2025 May 27]. Available from: <https://ordemdosmedicos.pt/files/pdfs/SbEJ-Declara%C3%A7%C3%A3o-da-Terceira.pdf>.
16. Direção-Geral da Saúde. Plano nacional de saúde 2021–2030: saúde sustentável: de tod@s para tod@s. 2022. [cited 2025 Sep 16]. Available from: https://pns.dgs.pt/files/2022/03/PNS-21-30_Versao-editada-1_Final_DGS.pdf.
17. Ministério da Saúde de Portugal. Despacho n.º 2905/2013: Estabelece disposições relativas à implementação do projeto "Cirurgia Segura, Salva Vidas". 2013. [cited 2025 Sep 16]. Available from: <https://diariodarepublica.pt/dr/detalhe/despacho/2905-2013-1937343>.
18. World Health Organization. WHO guidelines for safe surgery 2009: safe surgery saves lives. 2009. [cited 2025 Jun 15]. Available from: <https://iris.who.int/server/api/core/bitstreams/c2ea24bb-10f7-48e4-8f63-55932e817ddc/content>.
19. American College of Surgeons. Ernest A. Codman, MD, FACS, 1869–1940. 2025. [cited 2025 May 21]. Available from: <https://www.facs.org/about-acs/archives/past-highlights/codmanhighlight/>.
20. Dervishaj O, Wright KE, Saber AA, Pappas PJ. Ernest Amory Codman and the end-result system. *Am Surg.* 2015;81:12-5.
21. Howell J, Ayanian J. Ernest Codman and the end result system: a pioneer of health outcomes revisited. *J Health Serv Res Policy.* 2016;21:279-81.
22. Nakayama DK. Ernest Amory Codman and the end result idea in surgical quality. *Am Surg.* 2023;89:4237-40.
23. Nasca TJ, Philibert I, Brigham T, Flynn TC. The next GME accreditation system-rationale and benefits. *N Engl J Med.* 2012;366:1051-6.
24. Kravet SJ, Howell E, Wright SM. Morbidity and mortality conference, grand rounds, and the ACGME's core competencies. *J Gen Intern Med.* 2006;21:1192-4.
25. Kauffmann RM, Landman MP, Shelton J, Dmochowski RR, Bledsoe SH, Hickson GB, et al. The use of a multidisciplinary morbidity and mortality conference to incorporate ACGME general competencies. *J Surg Educ.* 2011;68:303-8.
26. Endicott KM, Zetervall SL, Rettig RL, Patel N, Buckley L, Sidawy A, et al. Use of structured presentation formatting and nsqip guidelines improves quality of surgical morbidity and mortality conference. *J Surg Res.* 2019;233:118-23.
27. Cromeens BP, Lisciandro RE, Brilli RJ, Askegard-Giesmann JR, Kenney BD, Besner GE. Identifying adverse events in pediatric surgery: comparing morbidity and mortality conference with the NSQIP-pediatric system. *J Am Coll Surg.* 2017;224:945-53.
28. Gurien LA, Ra JH, Kerwin AJ, Nussbaum MS, Crandall M, deVila J, et al. National surgical quality improvement program integration with morbidity and mortality conference is essential to success in the march to zero. *Am J Surg.* 2016;212:623-8.
29. Auspitz M, Cleghorn MC, Tse A, Sockalingam S, Quereshey FA, Okrainec A, et al. Understanding quality issues in your surgical department: comparing the ACS NSQIP with traditional morbidity and mortality conferences in a canadian academic hospital. *J Surg Educ.* 2015;72:1272-7.
30. Miller DC, Filson CP, Wallner LP, Montie JE, Campbell DA, Wei JT. Comparing performance of morbidity and mortality conference and national surgical quality improvement program for detection of complications after urologic surgery. *Urology.* 2006;68:931-7.
31. Institute of Medicine Committee on Quality of Health Care in America. To err is human: building a safer health system. In: Kohn LT, Corrigan JM, Donaldson MS, editors. Washington D.C.: National Academies Press; 2000.
32. Donaldson MS. Chapter 3 - an overview of to err is human: re-emphasizing the message of patient safety. In: Hughes RG, editor. Patient safety and quality an evidence-based handbook for nurses. Maryland: Agency for Healthcare Research and Quality; 2008.
33. Adam S, Odell M. An acute problem? A report of the national confidential enquiry into patient outcome and death. *Nurs Crit Care.* 2005;10:225-7.
34. Gray A. United Kingdom national confidential enquiry into perioperative deaths. *Minerva Anesthesiol.* 2000;66:288-92.
35. National Confidential Enquiry into Patient Outcome and Death. Common themes 2024. A summary of themes arising from NCEPOD reports relevant to all healthcare specialties. 2024. [cited 2025 Sep 16]. Available from: https://www.ncepod.org.uk/pdf/current/NCEPOD_Common_Themes_2024.pdf.
36. Mason M. The NCEPOD method – how the national confidential enquiry into patient outcome and death designs and delivers national clinical outcome review programmes. *J Patient Saf Risk Manag.* 2017;23:35-45.
37. Wysocki AP, Allen J, Rey-Conde T, North JB. Analysis of deficiencies in care following cholecystectomy. *J Visc Surg.* 2015;152:217-22.
38. Watters DA, Babidge WJ, Kiermeier A, McCulloch GA, Maddern GJ. Perioperative mortality rates in Australian public hospitals: the influence of age, gender and urgency. *World J Surg.* 2016;40:2591-7.
39. Stevens CL, Reid JL, Babidge WJ, Maddern GJ. Peer review of mortality after hepatectomy in Australia. *HPB.* 2020;22:611-21.
40. Stevens CL, Reid JL, Babidge WJ, Maddern GJ. Peer review of mortality after pancreaticoduodenectomy in Australia. *HPB.* 2019;21:1470-7.
41. Stevens CL, Brown C, Watters DAK. Measuring outcomes of clinical care: victorian emergency laparotomy audit using quality investigator. *World J Surg.* 2018;42:1981-7.
42. Raju RS, Guy GS, Majid AJ, Babidge W, Maddern GJ. The Australian and New Zealand audit of surgical mortality-birth, deaths, and carriage. *Ann Surg.* 2015;261:304-8.
43. Murshed I, Gupta AK, Camilos AN, Sabab A, Bacchi S, Kovoov JG, et al. Surgical interhospital transfer mortality: national analysis. *Br J Surg.* 2023;110:591-8.

44. Mansour LT, Brien S, Reid J, Maddern GJ. Peri-operative mortality following cholecystectomy in australia: potential preventability of adverse events. *World J Surg.* 2021;45:681-9.
45. Liu DS, Fayed A, Evans P, Bright T, Aly A, Duong C, et al. Understanding potentially preventable mortality following oesophago-gastric cancer surgery: analysis of a national audit of surgical mortality. *Ann Surg Oncol.* 2023;30:4950-61.
46. Jones CR, McCulloch GA, Ludbrook G, Babidge WJ, Maddern GJ. Deaths in incorrectly identified low-surgical-risk patients. *World J Surg.* 2018;42:1997-2000.
47. Chui JN, Papachristos AJ, Mechera R, Sidhu SB, Sywak MS, Lee JC, et al. Unexpected deaths after endocrine surgery: learning from rare events using a national audit of surgical mortality. *Br J Surg.* 2022;109:1164-71.
48. Bedrikovetski S, Kopunic HS, Procter N, Murshed I, De Fontgalland JS, Traeger L, et al. Use of the australian and new zealand audit of surgical mortality (ANZASM) to determine potentially preventable deaths after emergency general surgery. *Surgery.* 2025;184:109444.
49. Garcia Fuentes MJ, Gerk A, Campos L, Torres A, Wurdeman T, Kumar N, et al. Integrating comprehensive surgical, intensive, and emergency care systems into the Pan American Health Organization's health agenda. *Rev Panam Salud Publica.* 2025;49:e16.
50. Hyman GY, Salamea JC, Gerk A, Kumar N, Wurdeman T, Park KB, et al. Ecuador's national surgical strengthening plan: first in Latin America, provides hope for surgical care agenda. *Rev Panam Salud Publica.* 2024;48:e22.
51. Gerk A, Campos LN, Telles L, Bustorff-Silva J, Schnitman G, Ferreira R, et al. Expansion of national surgical, obstetric, and anaesthesia plans in Latin America: can Brazil be next? *Lancet Reg Health Am.* 2024;37:100834.
52. Gazzetta J, Makasa EM, Mwale M, Phiri C, Mulenga MJ, Mpabalwani MB, et al. Assessing the perioperative capacity in the republic of zambia in preparation for the first revision of the national surgical obstetric and anesthesia plan (NSOAP): a rapid survey method. *World J Surg.* 2025;49:1484-9.
53. Truché P, Shoman H, Reddy CL, Jumbam DT, Ashby J, Mazhiqi A, et al. Globalization of national surgical, obstetric and anesthesia plans: the critical link between health policy and action in global surgery. *Global Health.* 2020;16:1.
54. Mater Hospital. Guidelines for conducting morbidity & mortality meetings. 2018. [cited 2025 May 25]. Available from: https://svhprodaueph0st.blob.core.windows.net/media/svph/media/svph/pdfs/mhs/guidelines-for-conducting-m-m-meetings_final.pdf.
55. Safer Care Vitoria. A systems-focused framework for morbidity and mortality meetings. 2024. [cited 2025 May 21]. Available from: <https://www.safercare.vic.gov.au/sites/default/files/2024-08/SCV%20systems-focused%20Morbidity%20and%20Mortality%20Framework%20FINAL.pdf>.
56. World Federation of Societies of Anaesthesiologists. Morbidity & mortality tool kit for low and middle income countries (LMIC). 2013. [cited 2025 Sep 16]. Available from: <https://wfsahq.org/wp-content/uploads/MMTool-Kit-FINAL-VERSION.pdf>.
57. Canberra Health Services. Morbidity and mortality committees guideline. [cited 2025 Sep 16]. Available from: https://www.canberrahealthservices.act.gov.au/__data/assets/word_doc/0009/2064789/CHS-Morbidity-and-Mortality-Committee-Guideline_V1_20220406.docx.
58. Phong T, Dargon ELM, Nick Sevdalis. Morbidity & mortality conference manual. Imperial College of London. 2012. [cited 2025 Sep 16]. Available from: <https://www.imperial.ac.uk/media/imperial-college/medicine/surgery-cancer/pstcr/mmanualv1.1dec2012rev.pdf>.
59. Renganathana P, Sureshb VS. Morbidity and mortality meetings for improved patient care. 2025. [cited 2025 Sep 16] Available from: <https://www.kauveryhospital.com/kauverian-scientific-journal/morbidity-and-mortality-meetings-for-improved-patient-care/>.
60. Royal Australasian College of Surgeons. Guideline reference document for conducting effective morbidity and mortality meetings for improved patient care. 2017. [cited 2025 Sep 16]. Available from: https://www.surgeons.org/-/media/Project/RACS/surgeons-org/files/position-papers/2017-04-12_gdl_conducting_effective_morbidity_and_mortality_meetings_for_improved_patient_care.pdf.
61. Feinberg School of Medicine of Northwestern University. Mortality conference. 2025. [cited 2025 July 14]. Available from: <https://www.surgery.northwestern.edu/education/purplesurg-and-conferences/morbidity-mortality.html>.
62. Mayhew D, Mendonca V, Murthy BV. A review of ASA physical status - historical perspectives and modern developments. *Anaesthesia.* 2019;74:373-9.
63. Copeland GP. The POSSUM system of surgical audit. *Arch Surg.* 2002;137:15-9.
64. Copeland GP, Jones D, Walters M. POSSUM: a scoring system for surgical audit. *Br J Surg.* 1991;78:355-60.
65. Bilimoria KY, Liu Y, Paruch JL, Zhou L, Kmiecik TE, Ko CY, et al. Development and evaluation of the universal ACS NSQIP surgical risk calculator: a decision aid and informed consent tool for patients and surgeons. *J Am Coll Surg.* 2013;217:833-42.e1-3.
66. Epstein NE. Morbidity and mortality conferences: their educational role and why we should be there. *Surg Neurol Int.* 2012;3:S377-88.
67. Direção-Geral da Saúde. Comunicação eficaz na transição de cuidados de saúde. 2017. [cited 2025 Sep 16]. Available from: <https://normas.dgs.min-saude.pt/wp-content/uploads/2019/10/comunicacao-eficaz-na-transicao-de-cuidados-de-saude.pdf>.
68. Chan C, Pazandak C, Angelis D. Implementation of morbidity and mortality conference in a community hospital NICU and narrative review. *Front Pediatr.* 2023;11:1321296.
69. van den Tweel JG, Wittekind C. The medical autopsy as quality assurance tool in clinical medicine: dreams and realities. *Virchows Archiv.* 2016;468:75-81.
70. Stiven PN, Frampton CM, Lewis DR. Use of autopsy in general surgery: a comparison of practice and opinion. *ANZ J Surg.* 2007;77:722-6.
71. Rastan AJ, Gummert JF, Lachmann N, Walther T, Schmitt DV, Falk V, et al. Significant value of autopsy for quality management in cardiac surgery. *J Thorac Cardiovasc Surg.* 2005;129:1292-300.018.
72. Gomes A, Rocha R, Marinho R, Justino M, Sousa M, Tomás R, et al. Morbimortalidade anual num serviço de cirurgia geral: metodologia e análise de 2012. Amadora: Unidade Local de Saúde Amadora/Sintra; 2014.



Figura 1 – Exantema vermelho-vivo na região suprapúbica

com exantema viral.

Caso 2: Um adolescente de 16 anos, do sexo masculino, recorreu ao SU por exantema assintomático com três dias de evolução. Referia anorexia e mal-estar geral. Ao

exame objetivo, encontrava-se febril (38,5°C), fácies tóxica, e com exantema petequeial/purpúrico de distribuição acral (Fig. 2A, 2B), palmoplantar (Fig. 2C) e periorifical. Adicionalmente, objetivou-se língua em morango e petéquias no



Figura 2 – Exantema petequeial e purpúrico com distribuição acral (A, B) e afeção palmoplantar (C). Observa-se eritema e descamação perioral e perinasal e uma língua em morango (D).

palato mole (Fig. 2D). Colocou-se a hipótese de escarlatina, o doente foi internado e medicado com penicilina. Do estudo complementar, o teste rápido estreptocócico foi negativo e a IgM PvB19 foi positiva com IgG negativa. A biópsia cutânea foi compatível com exantema viral. Serologias repetidas após seis semanas revelaram IgM e IgG PvB19 positivas.

Caso 3: Um homem de 19 anos recorreu ao SU por exantema assintomático com dois dias de evolução. Referia gastroenterite autolimitada na semana anterior. Ao exame objetivo, constatou-se doente febril (38,1°C), com exantema petequial de distribuição acral (Fig. 3A, 3B), palmoplantar, dorsal e periorifical (Fig. 3C). As análises mostraram trombocitopenia. Colocou-se a hipótese de trombocitopenia autoimune ou vasculite. Na reavaliação após uma semana, constatou-se a resolução espontânea da dermatose e da trombocitopenia e serologias com IgM e IgG PvB19 positivas. Estas serologias foram repetidas passadas seis semanas com um aumento em quatro vezes do título de IgG.

Caso 4: Uma mulher de 65 anos recorreu ao SU por dermatose pruriginosa com dois dias de evolução, de início nos pés, com progressão proximal. A doente referia talalgia e artralguas das mãos. Negou episódios infecciosos recentes ou introdução de novos fármacos. Ao exame objetivo, observavam-se pápulas e placas eritematovioláceas dolorosas nos membros inferiores e superiores (Fig. 4A, 4B), incluindo palmas, e no tronco, assim como edema do tornozelo esquerdo. Colocou-se a hipótese de vasculite leucocitoclástica, confirmada por biópsia cutânea. Do estudo complementar, o único resultado positivo foi IgM e IgG PvB19 positivas. A doente cumpriu tratamento com prednisolona oral 0,5 mg/kg/dia e betametasona 0,1% creme, com resolução em duas semanas.

Caso 5: Uma mulher de 35 anos recorreu ao SU por dermatose com três semanas de evolução caracterizada

por pápulas eritematovioláceas nos membros inferiores, quadrantes inferiores do abdómen e antebraços. A doente referia ainda artralguas das mãos, talalgia e negou febre. A biópsia cutânea confirmou a hipótese diagnóstica de vasculite leucocitoclástica. O estudo complementar apenas demonstrou IgM e IgG PvB19 positivas que foram repetidas passadas seis semanas, verificando-se um aumento em quatro vezes do título da IgG e redução da IgM. A doente iniciou tratamento com prednisolona oral 0,5 mg/kg/dia e betametasona 0,1% creme. Posteriormente, referiu ter havido um surto de PvB19 na creche onde trabalhava, previamente ao início da dermatose. Este tem sido um caso desafiante, com episódios recorrentes de vasculite aquando da redução da dose de prednisolona oral. A doente iniciou recentemente azatioprina 150 mg/dia e mantém seguimen-

DISCUSSÃO

A manifestação mais comum de PvB19 em adolescentes é a SPPML.^{1,3} Outra manifestação é o exantema petequeial/purpúrico de padrão periflexural e periorifical,¹ sendo que os primeiros três casos correspondem a uma sobreposição deste último com a SPPML. Ambos têm bom prognóstico e prescindem de tratamento dirigido, sendo autolimitados.¹ Estes casos foram, inicialmente, diagnosticados incorretamente pela sua semelhança com outras patologias.

As vasculites cutâneas podem ter diversas etiologias, sendo as infecções responsáveis por 15% - 20%, principalmente infecções respiratórias superiores ou estreptocócicas. Os dois últimos casos correspondem a vasculites causadas pelo PvB19, uma manifestação rara deste vírus.

A infecção por PvB19 caracteriza-se por uma primeira fase de viremia com uma síndrome gripal ligeira seguida de uma segunda fase após duas semanas onde surgem manifestações como o exantema e/ou as artralgias.¹⁰ O conhecimento do comportamento bifásico deste vírus pode

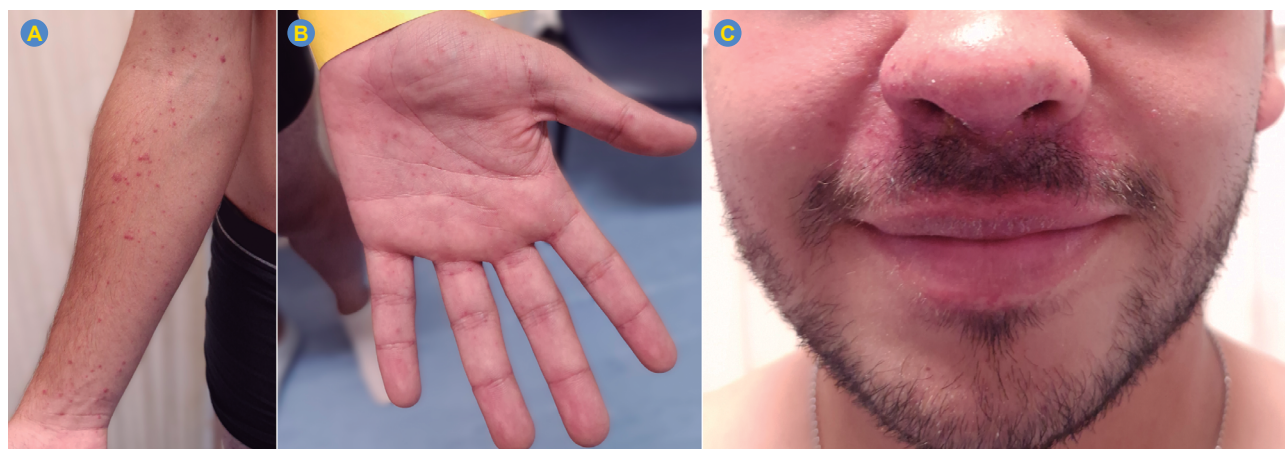


Figura 3 – Exantema petequial e purpúrico com distribuição acral (A, B). Observa-se eritema e descamação perioral e perinasal (C).



Figura 4 – Pápulas e placas eritematovioláceas nos membros inferiores (A, B)

facilitar o seu diagnóstico atempado.

Estes casos ilustram as manifestações clínicas diversas do PvB19 em adolescentes e adultos, que podem constituir um desafio diagnóstico pela sua semelhança com outras patologias, mas correspondem geralmente a situações autolimitadas e com bom prognóstico. Destaca-se o papel da história epidemiológica que, no quinto caso, teria motivado maior suspeição clínica se esclarecida *ab initio*. Reforçamos que o PvB19 deve ser considerado um grande imitador pela sua capacidade em imitar doenças que se apresentam com exantemas, incluindo outras doenças infecciosas, toxidermias, doenças autoimunes, podendo ainda imitar ou causar vasculites.

ACKNOWLEDGMENTS

Os autores declaram não ter utilizado ferramentas de inteligência artificial na elaboração do artigo.

CONTRIBUTO DOS AUTORES

ITA: Conceptualização, metodologia, recursos, redação e revisão crítica do manuscrito.

IS: Conceptualização, recursos, revisão crítica do manuscrito.

FSM: Recursos, revisão crítica do manuscrito.

GAS: Metodologia, revisão crítica do manuscrito.

PF: Administração do projeto, supervisão e validação.

Todos os autores aprovaram a versão final a ser publicada.

PROTEÇÃO DE PESSOAS E ANIMAIS

Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pelos responsáveis da Comissão de Investigação Clínica e Ética e de acordo com a Declaração de Helsínquia da Associação Médica Mundial atualizada em outubro de 2024.

CONFIDENCIALIDADE DOS DADOS

Os autores declaram ter seguido os protocolos do seu centro de trabalho acerca da publicação de dados.

REFERÊNCIAS

1. Mancini AJ, Shani-Adir A, Sidbury R. Other viral diseases. In: Bologna JL, Schaffer JV, Cerroni L, editors. *Dermatology*. Amsterdam: Elsevier; 2024. p.1437-60.
2. Rubin R. What to know about the recent rise in parvovirus b19 infections. *JAMA*. 2024;332:1226.
3. Smith PT, Landry ML, Carey H, Krasnoff J, Cooney E. Papular-purpuric gloves and socks syndrome associated with acute parvovirus B19 infection: case report and review. *Clin Infect Dis*. 1998;27:164-8.
4. Bloise S, Cocchi E, Mambelli L, Radice C, Marchetti F. Parvovirus B19 infection in children: a comprehensive review of clinical manifestations and management. *Ital J Pediatr*. 2024;50:261.
5. Russcher A, van Boven M, Benincà E, Verweik EJ, Molenaar de Backer MW, Zaaijer HL, et al. Changing epidemiology of parvovirus B19 in the Netherlands since 1990, including its re-emergence after the COVID-19 pandemic. *Sci Rep*. 2024;14:9630.
6. Anderer S. Uptick in parvovirus B19. *JAMA*. 2024;332:1043.
7. Marano G, Vaglio S, Pupella S, Facco G, Calizzani G, Candura F, et al. Human parvovirus b19 and blood product safety: a tale of twenty years of improvements. *Blood Transfus*. 2015;13:184-96.
8. Suzuki M, Watari T. Parvovirus B19 infection: a vasculitis masquerade in an elderly patient. *Am J Case Rep*. 2023;24:e939696.
9. Karadağ AS, Chen W. Great imitators in dermatology: part I. *Clin Dermatol*. 2019;37:173-4.
10. Heegaard ED, Brown KE. Human parvovirus B19. *Clin Microbiol Rev*. 2002;15:485-505.

CONSENTIMENTO DOS DOENTES

Obtido.

CONFLITOS DE INTERESSE

Os autores declaram não ter conflitos de interesse relacionados com o presente trabalho.

FONTES DE FINANCIAMENTO

Este trabalho não recebeu qualquer tipo de suporte financeiro de nenhuma entidade no domínio público ou privado.

Obstruction of Transplanted Kidney from Urinary Catheter Misplacement

Obstrução de Aloenxerto Renal Secundária a Sonda Vesical Mal Posicionada

Vítor FERNANDES ¹, Joana ANDRADE LOPES ¹, Alberto COSTA SILVA ²

Acta Med Port 2026 Jan;39(1):60-61 • <https://doi.org/10.20344/amp.23634>

Keywords: Incidental Findings; Kidney Transplantation; Urinary Catheterization/adverse effects
Palavras-chave: Achados Incidentais; Cateterização Urinária/efeitos adversos; Transplante de Rim

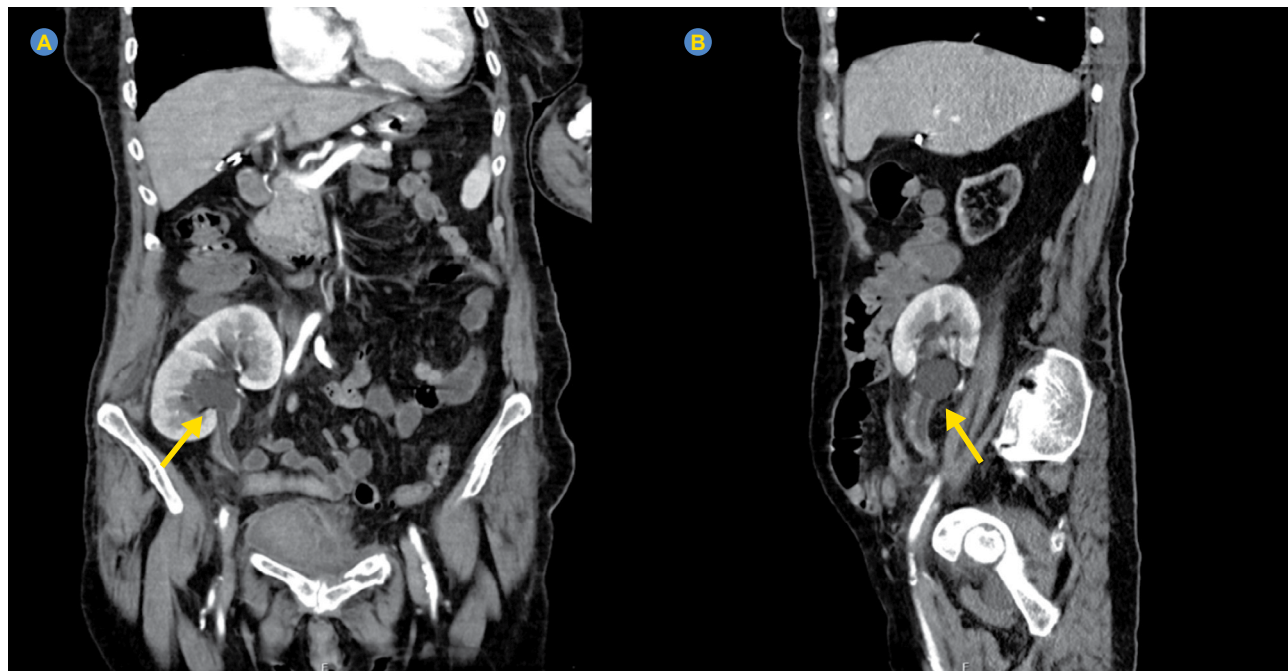


Figure 1 – Indwelling urinary catheter within the renal pelvis. The arrow indicates the catheter balloon.

A 71-year-old woman was admitted for an infected pelvic hematoma, 11 years post-kidney transplant. Baseline renal function was stable (serum creatinine 1.2 mg/dL). Following urinary catheterization, she developed progressive oliguria, with creatinine rising to 3.4 mg/dL.

Computed tomography imaging revealed malposition of the indwelling urinary catheter, which had been inadvertently inserted into the renal pelvis of the transplanted kidney (Fig. 1). No hydronephrosis was present on admission. Ultrasound-guided catheter replacement promptly led to resolution of oliguria and hydronephrosis, with recovery of kidney function to baseline.

This case highlights a rare but serious complication of urinary catheterization in kidney transplant recipients. Unlike prior reports identifying pre-existing hydronephrosis as a risk factor, this occurred in the absence of structural

abnormalities.¹ However, iliac fossa allograft placement with ureteroneocystostomy can result in altered anatomy, potentially predisposing to catheter misplacement. A simple preventive maneuver is a slight catheter withdrawal after balloon inflation to ensure correct bladder positioning.²

ACKNOWLEDGMENTS

The authors have declared that no AI tools were used during the preparation of this work.

AUTHOR CONTRIBUTIONS

VF, JAL: Study design, data analysis and interpretation, writing and critical review of the manuscript.

ACS: Data collection, critical review of the manuscript.

All authors approved the final version to be published.

1. Nephrology Department. Unidade Local de Saúde São João. Porto. Portugal.

2. Urology Department. Unidade Local de Saúde São João. Porto. Portugal.

✉ **Autor correspondente:** Vítor Fernandes. vita_fnds@hotmail.com

Revisão por/Reviewed by: Carla Nicolau 

Recebido/Received: 03/07/2025 - **Aceite/Accepted:** 23/09/2025 - **Publicado Online/Published Online:** 22/10/2025 - **Publicado/Publicado:** 02/01/2026

Copyright © Ordem dos Médicos 2026



PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

PATIENT CONSENT

Obtained.

REFERENCES

1. Bradley A, Sozener C. Incidentally discovered foley catheter placement into a transplanted kidney. *Urology*. 2015;86:e11-2.
2. European Association of Urology Nurses. Evidence-based guidelines for

CONFLICTS OF INTEREST

VF and ACS received payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from AstraZeneca.

JAL received payment or honoraria for lectures, presentations, speakers' bureaus, manuscript writing or educational events from Takeda - Farmacêuticos Portugal, Lda.; received support for attending meetings or travel from Bayer Portugal, Lda., and A Menarini Portugal Farmacêutica, S.A.

FUNDING SOURCES

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

best practice in urological health care: indwelling catheterisation. 2024. [cited 2025 Aug 17]. Available from: <https://nurses.uroweb.org/wp-content/uploads/EAUN-Guideline-indwelling-catheterisation-2024.pdf>.

Portuguese Consensus Guidelines for the Diagnosis and Treatment of Myasthenia Gravis

Recomendações Nacionais de Consenso para o Diagnóstico e Tratamento da Miastenia Gravis

Simão CRUZ ¹, Anabela MATOS ², Luís BRAZ ^{3,4}, Catarina FALCÃO CAMPOS ^{5,6}, João CERQUEIRA ^{7,8},
Luísa MEDEIROS ⁹, Ernestina SANTOS ^{10,11}, Luís SANTOS ¹², Andreia VEIGA ¹³
Acta Med Port 2026 Jan;**39**(1):62-75 • <https://doi.org/10.20344/amp.24089>

ABSTRACT

Myasthenia *gravis* is an autoimmune disease that affects the neuromuscular junction, mainly through the action of pathogenic antibodies such as those directed against the nicotinic acetylcholine receptor or, more infrequently, against the muscle specific kinase. Other important components of the autoimmune process include the complement pathway and B and T cell populations. Diagnosis is based on the finding of fatigable muscle weakness, which can affect several muscle groups, either in isolation or in variable combinations. Neurophysiological techniques and/or the detection of pathogenic antibodies in serum are also essential for the diagnosis of myasthenia *gravis*. Maintenance treatment was traditionally based on corticosteroids and non-steroidal immunosuppressants. Recently approved drugs, such as the terminal complement pathway inhibitors and the neonatal Fc receptor antagonists, are reshaping the treatment landscape, supported by robust evidence of an excellent combination of efficacy and safety. Although several international guidelines have been published in the last decade, some key questions remain without precise guidance. Hence, a group of nine experts from the Portuguese Neuromuscular Society has elaborated consensus guidelines that aim to provide detailed guidance on diagnostic workup and treatment, grounded both in published evidence and in clinical experience. Key novel aspects include step-by-step instructions for diagnostic workup, a set of diagnostic criteria, guidance on the use of complement inhibitors and neonatal Fc receptor antagonists, and tailored treatment algorithms according to antibody subgroup and clinical severity.

Keywords: Consensus; Myasthenia Gravis/diagnosis; Myasthenia Gravis/drug therapy

RESUMO

A miastenia *gravis* é uma doença autoimune da junção neuromuscular, cuja fisiopatologia consiste na produção de anticorpos patogénicos, mais frequentemente dirigidos contra o recetor nicotínico da acetilcolina e, mais raramente, contra a cinase específica do músculo. Outros elementos fisiopatológicos importantes incluem a cascata do complemento e as linhagens linfocitárias B e T. O diagnóstico assenta em fraqueza muscular fatigável, que pode afetar diversos grupos musculares, de forma isolada ou em combinações variáveis. A deteção sérica de anticorpos patogénicos e/ou a realização de estudos neurofisiológicos são também essenciais para o diagnóstico. O tratamento de manutenção baseia-se tradicionalmente na corticoterapia e em imunossuppressores não esteroides. Recentemente, têm surgido várias opções terapêuticas promissoras, como os inibidores da porção terminal do complemento ou os antagonistas do recetor Fc neonatal, que estão a transformar o cenário terapêutico da miastenia *gravis*, apoiados por evidência robusta de eficácia e segurança. Apesar da publicação de diversas recomendações internacionais ao longo da última década, existem várias questões importantes que carecem de orientações detalhadas. As presentes recomendações foram elaboradas por um grupo de nove especialistas da Sociedade Portuguesa de Estudos de Doenças Neuromusculares e são as primeiras recomendações portuguesas dirigidas à miastenia *gravis*. Nestas recomendações, produzidas por consenso e baseadas na evidência e na prática clínica, procura-se uniformizar a avaliação dos doentes com miastenia *gravis*, fornecer orientações concretas para a investigação diagnóstica dos casos suspeitos de miastenia *gravis* e apoiar as decisões referentes ao tratamento. Entre as principais novidades destas recomendações destacam-se: propostas de marcha diagnóstica e de critérios de diagnóstico, recomendações sobre instrumentos de avaliação da resposta terapêutica, posicionamento dos novos imunossuppressores e algoritmos terapêuticos adaptados ao serogrupo e à gravidade clínica.

Palavras-chave: Consenso; Miastenia Gravis/diagnóstico; Miastenia Gravis/tratamento farmacológico

1. Serviço de Neurologia. Unidade Local de Saúde Amadora/Sintra. Amadora. Portugal.
2. Serviço de Neurologia. Unidade Local de Saúde de Coimbra. Coimbra. Portugal.
3. Serviço de Neurologia. Unidade Local de Saúde S. João. Porto. Portugal.
4. Departamento de Neurociências e Saúde Mental. Faculdade de Medicina. Universidade do Porto. Porto. Portugal.
5. Serviço de Neurologia. Departamento de Neurociências e Saúde Mental. Unidade Local de Saúde Santa Maria. Lisboa. Portugal.
6. Centro de Estudos Egas Moniz. Faculdade de Medicina. Universidade de Lisboa. Lisboa. Portugal.
7. Serviço de Neurologia. Unidade Local de Saúde de Braga. Braga. Portugal.
8. Instituto de Investigação em Ciências da Vida e da Saúde. Escola de Medicina. Universidade do Minho. Braga. Portugal.
9. Consulta de Doenças Neuromusculares. Unidade Local de Saúde S. José. Lisboa. Portugal.
10. Serviço de Neurologia. Unidade Local de Saúde Santo António. Porto. Portugal.
11. Unidade Multidisciplinar de Investigação Biomédica. Instituto de Ciências Biomédicas Abel Salazar. Universidade do Porto. Porto. Portugal.
12. Consulta de Doenças Neuromusculares. Unidade Local de Saúde de Lisboa Ocidental. Lisboa. Portugal.
13. Serviço de Neurologia. Unidade Local de Saúde de Trás-os-Montes e Alto Douro. Vila Real. Portugal.

✉ **Autor correspondente:** Simão Cruz. simao.p.cruz@ulsasi.min-saude.pt

Revisto por/Reviewed by: João Martins , Rui André 

Recebido/Received: 12/10/2025 - **Aceite/Accepted:** 04/11/2025 - **Publicado Online/Published Online:** 15/12/2025 - **Publicado/Published:** 02/01/2026
Copyright © Ordem dos Médicos 2026



INTRODUCTION

Myasthenia *gravis* (MG) is the most common primary neuromuscular junction disease and is mediated by pathogenic antibodies, with particular emphasis on antibodies directed against the acetylcholine receptor (AChR), present in up to 90% of cases, and antibodies against muscle-specific kinase (MuSK), in up to 5%.¹⁻³ The essential element of the diagnosis of MG is the presence of fatigable muscle weakness, but the detection of pathogenic antibodies in serum and the neurophysiological demonstration of neuromuscular junction dysfunction help to confirm the diagnosis.³

Traditionally, the treatment of MG included pyridostigmine, oral corticosteroids, and conventional non-steroidal immunosuppressants, widely used in other neurological and systemic autoimmune diseases. Their use in MG is mainly supported by extensive clinical experience and expert recommendations, since available data derive largely from low-quality studies.^{2,3} In recent years, the treatment landscape of MG has changed substantially with the emergence of new drugs, such as neonatal Fc receptor antagonists (aFcRn) and complement cascade factor C5 inhibitors (C5i), which act through selective mechanisms and, in randomized double-blind controlled clinical trials, have demonstrated robust efficacy and safety profile.^{4,5}

Over the last decade, national guidelines from several countries have been published, as well as an international consensus guidance document and its updated version. However, these documents focus exclusively on therapeutic aspects and do not address diagnostic issues.⁴⁻¹¹

The main objective of these recommendations was to standardize clinical practice regarding the diagnosis and treatment of MG in Portugal and to provide detailed guidelines with practical applicability. In addition, we sought to fill some of the main gaps in the 2016 and 2021 international consensus guidance,^{10,11} namely: 1) to establish diagnostic criteria to improve reliability, particularly in seronegative MG; 2) to increase objectivity in clinical severity classification and define parameters to guide therapeutic decisions; 3) to provide practical recommendations for the use of conventional therapies with established benefit; and 4) to specify the role of rituximab and novel selective immunosuppressants.

METHODS

Members of the Portuguese Society for the Study of Neuromuscular Disease began developing these recommendations in September 2023. A working group was composed of nine neurologists with extensive experience in the care of MG patients and a deep knowledge of the geographical area where they develop their clinical activity. These experts were considered representative of the diversity of diagnostic and therapeutic practices across Portu-

guese healthcare institutions.

The scarcity of high-quality evidence regarding MG diagnosis and treatment precluded the use of strictly evidence-based methodologies. Thus, to produce these guidelines, a consensus-based methodology was chosen, using the RAND/UCLA Appropriateness Method,¹² a variant of the Delphi method used, for example, in the preparation of the 2016 and 2021 versions of the international consensus guidance.^{10,11}

Eight main topics were initially defined by the working group and, within these, the issues targeted by the guidance statements. The initial drafting of the recommendations for each topic was carried out by two members of the working group. The statements and their rationale were then individually shared with the other members, who were asked to rate each statement from 1 to 9 for appropriateness: a score between 1 and 3 would mean that the recommendation was inappropriate (i.e., the risks implied would clearly outweigh the benefits); a score of 4 to 6 would mean that the appropriateness was uncertain (i.e., the risk/benefit balance was unclear or there were no conditions to give an opinion on the topic under consideration); a score of 7 to 9 would mean that the recommendation was appropriate. For the scores below 9, comments and suggestions were provided to improve the content. The liaison element received individual appraisals of the other elements of the group, which were assessed by the drafting team, who analyzed the suggestions and prepared proposals for rewording or argued in favor of the initial text. The revised text was then shared again individually with the group members, and the evaluation process was repeated. Consensus was defined as a median score between 7 and 9, with no more than two votes below 7.

RECOMMENDATIONS

This section summarizes the main topics of these guidelines, all of which reached consensus as predefined. A full version is available in Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>) and includes: full guidance statements, literature summaries and lines of argumentation, and treatment algorithms. Median and range of ratings assigned by consensus group members to each guidance statement are also provided in Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>).

Topic 1: Diagnostic workup

1.1. Initial diagnostic workup

Diagnostic workup should follow a stepwise approach, adapted to the available resources of each

healthcare institution. Recommended strategies for suspected ocular or generalized MG are depicted in Figs. 1 and 2.

1.2. Utility of repeating antibody screening when initially negative

If the initial screening for AChR and MuSK antibodies is negative, and if a live cell-based assay (L-CBA) in an international reference laboratory is not feasible, the antibody testing should be repeated, preferably after at least six months.

1.3. Utility of screening for titin or striational antibodies

- Testing for titin or striational antibodies may be considered in all AChR antibody-positive patients with early symptom onset (before the age of 50), given the high predictive value for thymoma in this age group. This should not replace imaging screening.
- In late-onset patients, these antibodies provide no additional diagnostic or prognostic value.

1.4. Thymoma screening

- Chest computed tomography (CT) scan is the

preferred imaging modality for thymoma screening.

- Thymoma screening should be performed at diagnosis in all AChR antibody-positive patients.
- In seronegative MG, screening for thymoma should be considered.
- In MuSK antibody-positive MG, thymic abnormalities, including thymoma, are extremely rare: screening may nonetheless be considered.
- In AChR antibody-positive patients, initially without thymoma on CT or histology, repeat chest CT should be considered if a clinical exacerbation occurs that cannot be explained by well-established aggravating factors (listed in section 6.6).

Topic 2: Diagnostic criteria

2.1. Clinical manifestations with diagnostic utility

The cardinal clinical manifestation of MG is fatigable muscle weakness, which consists of the appearance or worsening of muscle weakness as a result of prolonged or repetitive exertion, and its improvement with rest. The clinical expression of this phenomenon is extremely varied and depends on the muscle groups that are affected in each patient. To determine the diagnostic certainty, the clinical signs

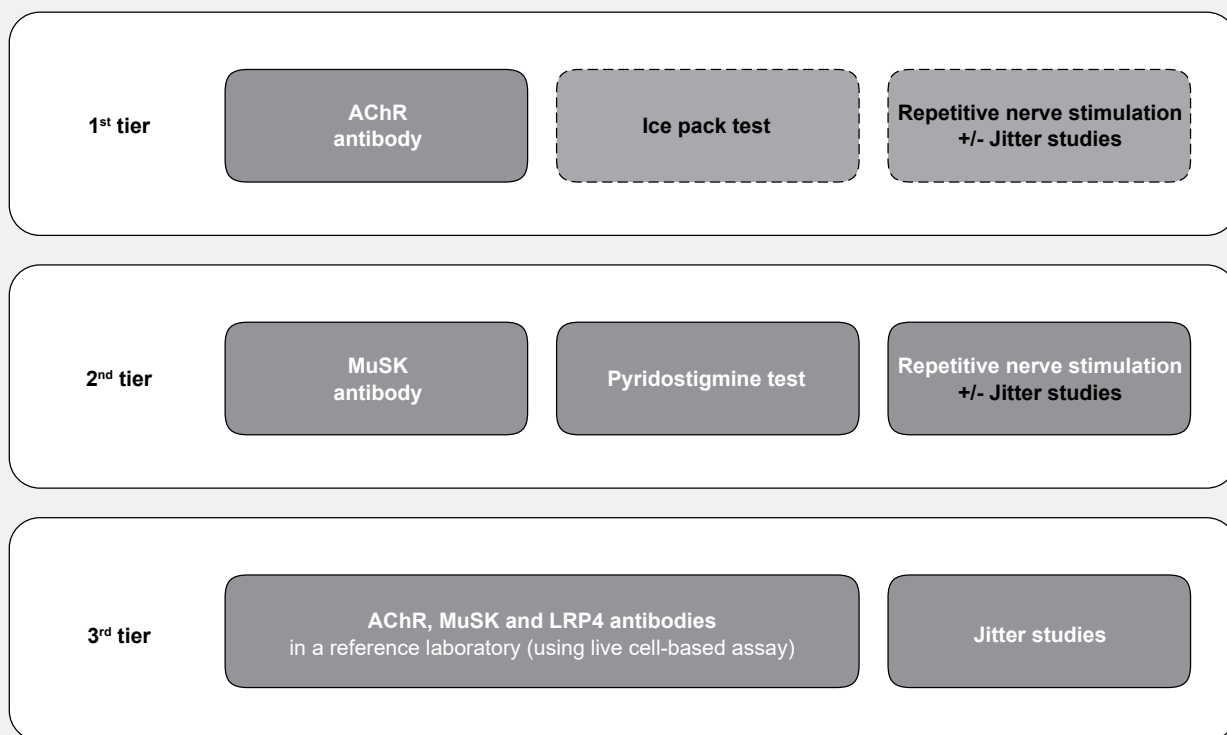


Figure 1 – Diagnostic workup of suspected cases of ocular MG. The gray background boxes with dashed outline and dark letters indicate that a particular test can be used at an earlier stage if it is easily accessible. Each tier should only take place if the previous tier was negative.

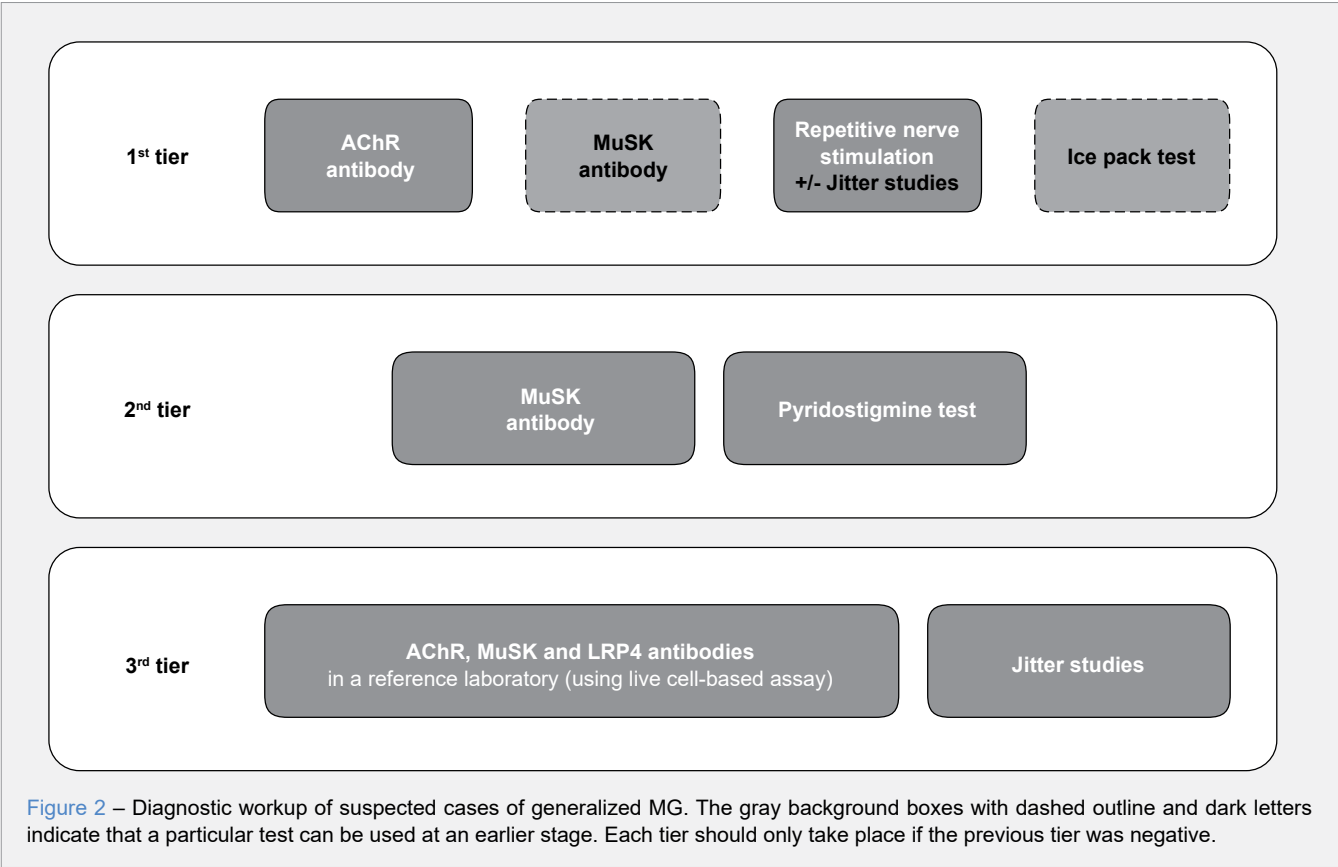


Figure 2 – Diagnostic workup of suspected cases of generalized MG. The gray background boxes with dashed outline and dark letters indicate that a particular test can be used at an earlier stage. Each tier should only take place if the previous tier was negative.

of MG were divided into two groups (Tables 1 and 2), according to their diagnostic specificity.

2.2. Definition of ocular MG

The term ‘ocular MG’ designates any pattern of muscle weakness that exclusively affects the external eye muscles (resulting in diplopia, with or without overt ocular movement paresis) or the eyelid levator muscle (resulting in eyelid ptosis). Concomitant weakness of the eyelid closure does not exclude this designation, but muscle strength in the remaining facial muscles, masticatory, oropharyngeal/laryngeal, respiratory, axial and limb muscles should be normal. This concept does not depend on disease duration.¹⁰

2.3. Diagnostic criteria for MG

Diagnostic criteria include one core, one confirmatory and four supportive criteria (Table 3). Depending on AChR or MuSK antibody status, the specificity of the clinical signs, and the presence of supportive criteria, MG diagnosis can be classified into three levels of certainty: definitive (seropositive or seronegative), probable, and possible (Fig. 3). Probable and, especially, possible MG should be regarded as working diagnoses and should prompt a thorough reassessment of differential diagnoses as well as an active search for elements to upgrade the level of certainty. Invasive, high-risk or costly treatments must be avoided in possible MG and should be selected carefully in probable MG cases.

Table 1 – Clinical signs compatible with and very specific to the diagnosis of MG

• Fatigable muscle weakness: unequivocal appearance or worsening (ideally measurable or quantifiable) of weakness in any muscle group during physical examination
• Unilateral or asymmetric eyelid ptosis with variable side and severity between observations
• Eyelid ptosis with Cogan’s sign and/or curtain sign
• Variable pattern of ocular movement paresis between observations
• Ocular movement paresis not consistent with a single cranial nerve or central nervous system lesion, or with an orbital myopathy
• Painless weakness on chewing and involuntary jaw opening after 20 seconds of maintained pressure over the mentum

Table 2 – Clinical signs compatible with but nonspecific to the diagnosis of MG

• Eyelid ptosis with concomitant weakness of eyelid closure
• Symmetrical bilateral eyelid ptosis or unilateral ptosis without variability of side or severity between observations
• Diplopia without clinically evident ocular movement paresis, particularly if intermittent
• Any pattern of ocular movement paresis compatible with an isolated lesion of cranial nerves (without pupillary dysfunction) or of a central nervous system location
• Symmetrical facial weakness, affecting both the upper and the lower face or only the eyelid closure
• Flaccid dysarthria and/or nasal dysphonia
• Vocal cord paralysis, with or without clinically audible stridor
• Oropharyngeal dysphagia
• Tongue weakness
• Weak and ineffective cough
• Orthopnea and paradoxical breathing pattern
• Head drop
• Neck flexion weakness
• Limb-girdle muscle weakness

Topic 3: Important concepts and assessment of treatment response

3.1. Post-intervention status

Among the several concepts developed by the Myasthenia Gravis Foundation of America (MGFA) to designate the clinical status after a therapeutic intervention,¹³ three stand out as the most useful:

- Complete stable remission: absence of MG symptoms and signs for at least one year, in the absence of any treatment for the disease in this period.
- Pharmacological remission: identical to complete stable remission but with ongoing MG treatment. Pyridostigmine is excluded as its use indicates residual muscle weakness.
- Minimal manifestations (MM): no symptoms or functional limitations due to MG but examination reveals muscle weakness, other than isolated eyelid closure weakness.

3.2. Clinical classification

The MGFA clinical classification, developed with the

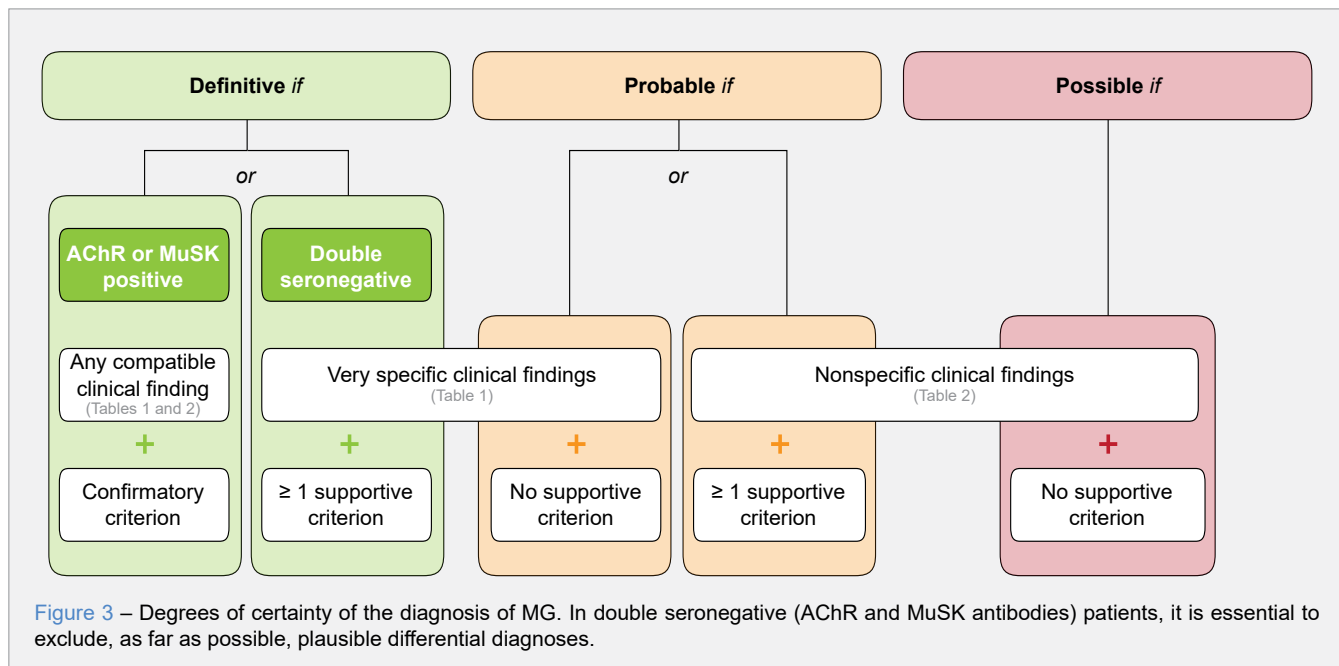
aim of standardizing the grading of clinical severity, establishes five classes of increasing severity.¹³ Despite the usefulness of this classification, even in clinical practice, its main limitation is the unclear distinction between the three intermediate classes, corresponding to mild, moderate and severe generalized MG. Therefore, these guidelines propose complementary definitions based on the functional impact of non-ocular myasthenic symptoms [Appendix 2, Table 1 (Appendix 2: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15825>)].

3.3. Therapeutic goals

- The goal of MG treatment is to achieve 'remission' or a 'minimal manifestations' status, with no side effects or only with mild side effects (mild symptoms, not requiring a targeted intervention), as proposed by the 2016 international consensus guidance.¹⁰
- In addition to the previous statement, we recommend that after achieving 'remission' or 'minimal

Table 3 – Diagnostic criteria for MG

<u>Core criterion:</u> at least one clinical sign compatible with the diagnosis of MG, regardless of whether it is very specific or nonspecific
<u>Confirmatory criterion:</u> AChR or MuSK antibodies
<u>Supportive criteria:</u>
• Low frequency repetitive nerve stimulation compatible with a postsynaptic dysfunction of neuromuscular transmission
• Abnormal <i>jitter</i> studies consistent with neuromuscular junction dysfunction, after excluding muscle, peripheral/cranial nerve, nerve root, or lower motor neuron disease
• Clear improvement of myasthenic signs on physical examination after pyridostigmine intake
• Positive ice pack test (in cases with overt eyelid ptosis)
• Positive LRP4 antibody



manifestation', corticosteroid maintenance dose should ideally not exceed 5 mg/day of prednisolone (or equivalent), although 7.5 mg/day might be reasonable if reaggravation occurs with a lower dose.

3.4. Instruments for the evaluation of therapeutic response in clinical practice

- During the follow-up of patients with MG, specific symptoms and signs of the disease should be evaluated regularly. For this purpose, we recommend routine application of the Activities of Daily Living scale (MG-ADL), ideally combined with another scale incorporating physical examination findings (e.g., MG composite).
- During follow-up, patients should be regularly asked about their quality of life and overall satisfaction with disease control.

3.5. Serial AChR or MuSK antibody testing

- Therapeutic decisions in AChR antibody-positive MG should not be based on antibody titers. Serial testing is not recommended for monitoring treatment response.
- In MuSK antibody-positive MG, serial titers may support interpretation in suspected relapses or when response to treatment remains uncertain after clinical evaluation.

Topic 4: Symptomatic treatment

4.1. Indications for initiating pyridostigmine

Pyridostigmine should be used in the initial treatment phase for all patients with symptomatic MG, regardless of severity and serological subgroup.

4.2. Initial dose and titration

- We recommend starting with 30 mg (half tablet) administered three or four times daily during periods of the day when the patient expects to be physically active. There is no benefit in administration at bedtime or during nocturnal sleep period.
- If the drug is well tolerated but symptoms persist, it may be increased after three to four days to a dose of 60 mg (one tablet) four times daily. If required and well tolerated, it may be increased up to six daily doses of 60 mg or up to a maximum dose of 90 mg in four or five daily doses.
- In MuSK antibody-positive MG, titration should be slower and with close monitoring for clinical worsening or adverse effects.

4.3. Indications for discontinuation of pyridostigmine

- Generally, in patients who are concomitantly receiving immunosuppressive drugs, discontinuation of these drugs should be preceded by successful withdrawal of pyridostigmine, as tolerance of its discontinuation without clinical

worsening indicates that treatment goals have been achieved.

- In persistently asymptomatic patients, pyridostigmine tapering (e.g., reducing by 30 to 60 mg per week) should be considered until complete withdrawal.
- In patients in myasthenic crisis requiring invasive mechanical ventilation (IMV), pyridostigmine should be temporarily stopped due to the risk of increased bronchial secretions and bronchospasm.

4.4. Other symptomatic treatments

No other drugs are recommended for symptomatic treatment of MG.

Topic 5: Maintenance immunosuppressive treatment

5.1. Indications for initiating immunosuppressive treatments

- Immunosuppression should be offered to patients with mild but bothersome clinical manifestations, including ocular MG, when therapeutic goals are not achieved with pyridostigmine monotherapy.
- Immunosuppression should be started upfront in patients with moderate (class III) or severe (class IV) generalized manifestations or in myasthenic crisis (MGFA class V), as sustained control is unlikely with pyridostigmine and traditional fast-acting immunomodulatory therapies alone.

5.2. Chronic corticosteroid therapy

5.2.1. Indications as a first line

- Corticosteroids are the most effective oral immunosuppressive agent in MG and should be the first-line treatment in eligible patients meeting the criteria in section 5.1. Caution should be observed with chronic use in patients at risk for serious adverse effects (e.g., glaucoma, osteoporosis, diabetes mellitus with poor glycemic control).

5.2.2. Titration, maintenance and weaning schemes

- Ocular MG, mild generalized MG, and moderate generalized nonbulbar MG (MGFA classes I, IIa, IIb, and IIIa)
 - Start prednisolone at a dose of 10 mg/day (or equivalent) and increase by 5 to 10 mg every five to seven days until symptoms resolve or a maximum 1 mg/kg/day (or 100 mg/day) dose is reached.
 - Maintain maximum dose, or the one that

allowed resolution of symptoms, for at least four weeks and no longer than eight weeks, to prevent serious adverse effects and poor compliance.

- Tapering schedule depends on compliance, comorbidities (notably diabetes mellitus with poor glycemic control) and clinical context. Full suggestions of tapering schedules can be found in Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>).
- Moderate generalized bulbar MG, severe generalized MG and myasthenic crisis (MGFA classes IIIb, IV and V).
 - Induction schedule will depend on severity and context:
 - Patients with MG classes IIIb or IV should ideally be admitted to the hospital. After starting treatment with intravenous immunoglobulins (IVIg) or plasmapheresis, begin oral prednisolone at a dose of 1 to 1.5 mg/kg/day. If admission, or at least a course of IVIg / plasmapheresis as outpatient, are not feasible, follow the ascending titration schedule suggested above to prevent steroid-induced exacerbation.
 - Patients with myasthenic crisis should be admitted to an Intensive Care Unit (ICU). Concomitantly with a course of plasmapheresis or IVIg, start oral prednisolone at a dose of 1 to 1.5 mg/kg/day (maximum 100 mg/day).
 - Maintain maximum dose for at least four weeks and no longer than eight weeks, to prevent serious adverse effects and poor compliance.
 - Tapering schedule depends on compliance, comorbidities (notably diabetes mellitus with poor glycemic control) and clinical context. Full suggestions of weaning schedules can be found in Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>).

5.2.3. Surveillance and prevention of corticosteroid adverse effects

See Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>).

24089/15824).

5.3. Traditional nonsteroidal immunosuppressants (NSI)

5.3.1. Indications for its use in MG

- Using a traditional NSI alone:
 - If corticosteroid therapy is contraindicated or refused by the patient.
- Using a traditional NSI upfront, combined with corticosteroids:
 - If there is a high risk of steroid-related adverse effects, based on the patient's comorbidities (e.g., diabetes *mellitus*, osteoporosis, glaucoma).
 - If the treating neurologist finds that adequate control with prednisolone monotherapy at a safe dose is unlikely.
- Using a traditional NSI as add-on drug in patients under corticosteroid therapy:
 - If adverse effects of corticosteroid therapy appear and are considered relevant by the patient and/or the treating physician.
 - If clinical response has been insufficient after a period of corticosteroid therapy of adequate duration and dose (dose up to 1 mg/kg/day for at least six to eight weeks).
 - If relapse occurs when tapering prednisolone to 7.5 mg/day or below.

5.3.2. Choice of drug to use

- Traditional NSIs are, in MG, mainly an adjunct therapy aimed essentially at maintaining the effect of highly effective therapies whose long-term use is limited by safety (corticosteroids) or logistics (new immunosuppressants, IVIg, and plasmapheresis).
- There is no foreseeable added benefit in the sequential use of more than two traditional NSIs if each of them has been stopped for inefficacy, despite adequate dose and duration.
- Azathioprine and mycophenolate mofetil are first-line options among traditional NSIs, either in ocular or generalized MG. Methotrexate can be an alternative option.
- Drug choice should be individualized, based on comorbidities, possible drug interactions and required speed of effect.
- In the current treatment landscape, cyclophosphamide, cyclosporine, and tacrolimus should not be used in the treatment of MG.

5.3.3. Titration and maintenance dose

See Appendix 2, Table 2 (Appendix 2: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15825>).

5.3.4. Surveillance and prevention of NSI adverse effects

See Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>).

5.4. Rituximab

5.4.1. Indications for its use in MG

- MuSK antibody-positive MG – rituximab is recommended in all cases for whom corticosteroids are ineffective, not tolerated or refused.
- AChR antibody-positive MG – rituximab may be considered in the following scenarios:
 - In mild generalized MG (MGFA class II)
 - As add-on if corticosteroid therapy is insufficiently effective.
 - In place of corticosteroids (if refusal or non-compliance), when the first-line treatment, an adequate trial with pyridostigmine and a traditional NSI, is not effective.
 - In moderate generalized bulbar MG (MGFA class IIIb) or severe (IVa and b), as possible first-line if refusal or non-compliance to corticosteroids.
 - In myasthenic crisis (MGFA class V), as possible first-line treatment if there's refusal or non-compliance to corticosteroids, after initial response to IVIg or plasmapheresis. In this setting, IgG levels should be near normal before starting rituximab.

5.4.2. Dosage regimens

- Dose: the choice of a high-dose schedule (option A: two administrations of 1000 mg, two weeks apart; option B: 375 mg/m², weekly for four consecutive weeks) or a reduced-dose schedule (e.g., 2 x 500 mg administrations two weeks apart; 375 mg/m² in two administrations two weeks apart) depends on disease duration, prior treatment response or refractoriness, and the patient's infectious risk profile.

- Treatment should be repeated in the following situations:
 - When the clinical response is considered sufficient, consideration may be given to resuming only in case of a clinical relapse, although this implies a careful clinical follow-up and facilitated access to the healthcare team as soon as first symptoms reappear.
 - If the initial clinical response is partial, treatment may be repeated when clinical worsening is observed, ensuring that a minimum interval of approximately 6 months has elapsed since the last dose.
 - If the clinical response is not considered significant, a second cycle, eventually with a higher dose, may be attempted in mild generalized (MGFA classes IIa or b) or moderate nonbulbar MG (IIIa). In more severe cases, switching to therapies with higher expected efficacy (i.e., C5 inhibitors or neonatal Fc receptor antagonists) is preferable.

5.4.3. Surveillance and prophylaxis

See Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>).

5.5. Neonatal Fc receptor antagonists and complement C5 inhibitors

5.5.1. Indications for its use in MG

- Complement C5 factor inhibitors (C5i) and neonatal Fc receptor antagonists (aFcRn) should be used mainly in clinical situations requiring high efficacy and rapid improvement.
- The use of these drugs is recommended – ideally as a bridging therapy – in the following indications:
 - In mild generalized MG (MGFA classes IIa or b) or moderate nonbulbar (IIIa) without significant clinical improvement (i.e., ≥ 2 -point reduction on the MG-ADL scale or ≥ 3 -point reduction on MG composite) after at least 2 cycles of rituximab, regardless of previously used therapies.
 - In moderate bulbar (MGFA class IIIb) or severe MG (IVa and b), without significant clinical improvement after corticosteroid therapy with adequate dose and duration.
 - In moderate bulbar (MGFA class IIIb) or

severe MG (IVa and b), without significant clinical improvement after a single cycle of rituximab, in the event of steroid refusal or non-compliance.

- In moderate bulbar (MGFA class IIIb) or severe MG (classes IVa and b), with relapse when tapering prednisolone to ≤ 7.5 mg/day, despite adequate trials with two traditional NSIs.
- In myasthenic crisis (MGFA class V), with failure of ventilatory weaning and nasogastric or gastrostomy tube removal after an initial course of one of the traditional fast-acting immunomodulatory treatments (IVIg or plasmapheresis) plus an additional course of the other not initially used traditional fast-acting treatment (performed one to two weeks after completion of initial treatment) plus oral prednisolone at a dose of 1 mg/kg/day for at least four weeks (in parallel with IVIg and/or plasmapheresis trials).

5.5.2. Choice of drug to use

- C5i can only be used in generalized AChR antibody-positive MG. aFcRn can be used in AChR antibody-positive MG and in the other serogroups.
- Based on the available evidence, aFcRn and C5i should be considered equally effective in AChR antibody-positive MG. Safety profile and dosing schedules should guide the choice between these two pharmacological groups.
- Within the aFcRn group, the choice between efgartigimod (intravenous or subcutaneous) and rozanolixizumab (subcutaneous) should be individualized and based on criteria such as patient preference for route and frequency of administration, and patient's adherence.
- Within the C5i group, due to its dosing advantage, ravulizumab should be used preferentially over eculizumab. Zilucoplan may be a suitable alternative in selected cases, depending on the patient's preference and compliance profile.

5.5.3. Dosing schedules

- Eculizumab (intravenous): induction at 900 mg weekly for four weeks; maintenance starts at 1200 mg at week five, then 1200 mg 2/2 weeks.

- Ravulizumab (intravenous): induction with 2400 mg (40 - 59 kg), 2700 mg (60 - 99 kg), or 3000 mg (≥ 100 kg) as a single dose; maintenance with 3000 mg (40 - 59 kg), 3300 mg (60 - 99 kg), or 3600 mg (≥ 100 kg) after two weeks, then 8/8 weeks.
- Zilucoplan (subcutaneous): a daily administration of a weight-adjusted dose [16.6 mg (< 56 kg), 23 mg (≥ 56 and < 77 kg) or 32.4 mg (≥ 77 kg)].
- Efgartigimod (intravenous): each cycle consists of a weekly administration of 10 mg/kg for four consecutive weeks.
- Efgartigimod (subcutaneous): each cycle consists of a weekly administration of 1000 mg for four consecutive weeks.
- Rozanolixizumab (subcutaneous): each cycle consists of a weekly administration of a weight-adjusted dose [280 mg (≥ 35 and < 50 kg), 420 mg (≥ 50 and < 70 kg), 560 mg (≥ 70 and < 100 kg) or 840 mg (≥ 100 kg)] for six consecutive weeks.

5.5.4. Treatment duration

- C5i and aFcRn should ideally be used transiently, as bridging therapy until the expected onset of therapeutic effect of a traditional NSI used concomitantly. However, if significant clinical improvement has occurred (i.e., ≥ 2 -point reduction on the MG-ADL scale or ≥ 3 points on the MG composite) with a C5i or an aFcRn, and this benefit has been lost upon taper or discontinuation of this drug, treatment should be resumed, and concomitant traditional NSI dose adjustment or replacement should be considered.
- For C5i tapering, we recommend to gradually reduce the dose and frequency of administration until withdrawal, once maximum sustained clinical benefit is achieved and concomitant NSI effect is expected to be already fully established, based on what is known about the maximum time required for the onset of action of each NSI.
- Regarding efgartigimod:
 - If after the first cycle there is no significant improvement or if the total score on the MG-ADL scale remains ≥ 5 points ($> 50\%$ attributable to non-ocular items), the second cycle should be performed four weeks after the last infusion.
 - If significant improvement occurs after

the first cycle and if the total score on the MG-ADL scale is < 5 points, a second cycle should be performed only if the initial improvement has been lost. In this case, repeat treatment should occur only when reaggravation begins and at least four weeks after completion of the previous cycle. This interval should determine the periodicity of subsequent cycles.

- For rozanolixizumab, data on repeated cycles are insufficient to issue recommendations.

5.5.5. Prophylaxis

- Treatment with C5i carries a high risk of infection by encapsulated bacteria, especially *Neisseria meningitidis*. Therefore, vaccination and some prophylactic measures are mandatory [see Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>)].
- FcRn antagonists do not require prior or regular blood tests or specific vaccinations.

5.6. Immunoglobulins and plasmapheresis in maintenance treatment

5.6.1. Indications

- IVIg as maintenance treatment should be restricted to selected cases of generalized MG (especially with AChR antibody-positive) that remain moderate or severe despite adequate trials with prednisolone, rituximab, and an aFcRn or C5i.
- Plasmapheresis as maintenance treatment should be restricted to selected cases of generalized AChR or MuSK antibody-positive MG that remain moderate or severe despite adequate trials with prednisolone, rituximab, an aFcRn, IVIg, and a C5i (in case of AChR antibody-positive MG).
- Both IVIg and plasmapheresis should ideally be used as a bridging therapy, until the effect of a traditional NSI is expected to be fully established.

5.6.2. Dose and frequency of treatments

- IVIg: induction cycle with a dose of 2 g/kg over two to five days, followed by maintenance cycles with a lower dose (e.g., 0.4 to 1 g/kg). Maintenance cycles should be tailored to the duration of each patient's clinical response: most commonly the interval is around four weeks, although a few patients

might require more frequent dosing.

- Plasmapheresis: induction cycle with three to five sessions every other day; maintenance cycles with one to three sessions on alternate days, with approximately monthly periodicity.

Topic 6: Myasthenic crisis

6.1. Definitions

- We recommend using the definitions proposed in the 2016 international consensus guidance¹⁰:
 - Manifest myasthenic crisis is defined as worsening of myasthenic weakness requiring invasive mechanical ventilation (IMV) or non-invasive ventilation (NIV) to avoid intubation.
 - Imminent myasthenic crisis is defined as rapid clinical worsening which, in the opinion of the treating physician, is likely to progress to manifest myasthenic crisis in the short term (days or weeks).
 - Exacerbation is a term that should be applied to patients who previously met the definition of remission or minimal manifestations but have recurrence of symptoms exceeding those allowed by these definitions, i.e. they are no longer asymptomatic.

6.2. Red flags

- The following clinical signs should prompt suspicion of respiratory muscle involvement and consideration of a myasthenic crisis:
 - Staccato speech at rest.
 - Use of accessory respiratory muscles (e.g., scalenes, sternocleidomastoids).
 - Intolerance to supine position due to orthopnea.
 - Paradoxical breathing pattern (abdominal retraction on inhalation and expansion during exhalation).
 - Inability to take a deep breath and count aloud at least to 20 on one single breath (this sign should only be considered if adequate patient cooperation is ensured).
 - Weak and ineffective cough.

6.3. Indications for hospital admission

- We recommend that all patients who meet the definition of manifest or imminent myasthenic crisis, or severe exacerbation (MGFA classes IVa or b) be admitted to hospital.
- Admission should also be considered in the event of moderate bulbar exacerbation (MGFA class IIIb).

- In manifest or imminent myasthenic crisis, the possibility of ICU admission should be promptly discussed.
- Arterial blood gas abnormalities appear late in the evolution of ventilatory dysfunction caused by myasthenic weakness and should not outweigh clinical signs when deciding ICU admission or ventilatory support (invasive or non-invasive).

6.4. Supportive treatment considerations in exacerbations with severe oropharyngeal and respiratory muscle involvement

- In MG patients with respiratory distress, early initiation of bilevel positive pressure (BiPAP) NIV, with airway clearance measures, may prevent the need for IMV.
 - In these patients, NIV should be initiated before hypercapnia develops.
 - The existence of overt weakness of facial muscles and difficulty managing secretions should not be considered contraindications to NIV.
- Pyridostigmine should be stopped after tracheal intubation to decrease oropharyngeal and respiratory secretions. However, pyridostigmine does not need to be stopped when the patient is on NIV and should be restarted at appropriate doses when weaning from IMV is planned.
- After extubation, early use of NIV should be considered, as it might increase the likelihood of success and decrease the risk of reintubation.

6.5. Fast-acting immunomodulatory treatments

- All patients who meet the indications for admission listed above should receive treatment with IVIg or plasmapheresis.
- Choice between IVIg and plasmapheresis depends on availability, comorbidities and current clinical status.
- Factors favoring plasmapheresis over IVIg, in hospitals where both options are available:
 - Manifest myasthenic crisis.
 - MuSK antibody-positive MG.
 - Chronic kidney disease.
 - Hypercoagulable states.
 - Severe arterial disease.
- In patients who do not have any of the factors listed above, the following factors may favor the choice of IVIg over plasmapheresis:
 - Active sepsis.
 - Advanced age.
 - Significant cardiac comorbidities (namely,

- heart failure).
- Hemorrhagic diathesis or recent major bleeding.
- Plasmapheresis can preferably be performed via peripheral venous access when feasible.
- In the treatment of manifest or imminent myasthenic crisis, the number of plasmapheresis sessions to be performed should be guided by clinical response, but usually it is not necessary to exceed a total of five to eight sessions.
- For patients receiving ventilatory support (invasive or non-invasive), daily plasmapheresis sessions may be considered and discussed with the medical team to promote faster clinical improvement.
- Treatment of myasthenic crisis with IVIg should use a total dose of 2 g/kg over two to five days.

6.6. Precipitating factors

- In the face of an exacerbation of the clinical manifestations of MG, the most common precipitating factors should be considered, namely:
 - Suboptimal dose or rapid tapering of immunosuppressive drugs.
 - Acute infection.
 - Recent surgery.
 - Pregnancy, childbirth, or puerperium.
- If these precipitating factors are absent, concurrent medications should be reviewed in order to assess whether there is a plausible causal association.
 - Although in most cases the evidence for causal association is limited, the following pharmacological groups have been especially associated with the onset or exacerbation of clinical manifestations of MG:
 - Immune checkpoint inhibitors.
 - D-Penicillamine.
 - Chloroquine and hydroxychloroquine.
 - Classes Ia and Ic antiarrhythmics (especially propafenone).
 - Aminoglycoside antibiotics (except tobramycin), macrolides and fluoroquinolones.
 - Botulinum toxin.
 - Magnesium (especially intravenous).
 - Potentially respiratory center depressant drugs, namely opioids and benzodiazepines (especially intravenous and at high doses).
 - Statins.
 - Beta-adrenergic blockers and calcium channel blockers.

- None of these drugs are absolutely contraindicated in MG nor should they be discontinued if they were already in chronic use at the time of the onset of symptoms of the disease. However, de novo use should be avoided if equivalent and presumably safer therapeutic alternatives exist.

Topic 7: Thymectomy

7.1. Indications (based in 2016 international consensus guidance¹⁰):

- Thymectomy is indicated in all patients with thymoma.
- In MG without thymoma, thymectomy may be considered in the following situations:
 - Early in the course of generalized AChR antibody-positive MG, if age of onset between 18 and 50 years.
 - It should be strongly considered in patients with AChR antibody-positive MG with poor response or intolerable adverse effects from initial immunotherapy in an appropriate regimen.
 - It may be considered in patients with seronegative generalized MG if response to immunosuppressants is unsatisfactory or to minimize adverse effects.
 - It may be considered in patients with ocular AChR antibody-positive MG if response to pyridostigmine is inadequate and if immunosuppressants are refused, not tolerated or ineffective.
- Current evidence does not support thymectomy in MuSK or LRP4 antibody-positive MG (without concomitant AChR antibody).
- Thymectomy in the context of MG is an elective procedure and should ideally be performed when the patient is stable and surgery is considered safe.

7.2. Use of fast-acting immunomodulatory treatments before thymectomy and other surgeries

- In patients who are about to undergo thymectomy or other surgical procedure and who are in remission or in a state of minimal manifestations, a pre-surgical treatment, namely with IVIg or plasmapheresis, is not recommended.
- Preoperative treatment may be used to prevent severe exacerbation or myasthenic crisis in patients with persistent moderate or severe MG (MGFA classes III or IV).
- The choice between IVIg and plasmapheresis should follow the criteria listed in 6.5.

- The use of oral corticosteroids at the time of thymectomy, even at high doses, is not contraindicated nor deleterious.

Topic 8: Pregnancy, childbirth and breastfeeding [see full version in Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>)]

8.1. Family planning and MG treatment in women of reproductive age

- Pregnancy in women with MG should be planned and ideally should occur during a stable phase of the disease.
- Regarding the treatments used in MG:
 - Pyridostigmine, prednisolone and azathioprine are generally considered safe in pregnancy.
 - Mycophenolate mofetil and methotrexate should not be prescribed to women of reproductive potential.
 - Rituximab can be used in women of childbearing age, but conception should ideally occur at least four months after the last infusion.
 - Complement inhibitors and FcRn antagonists may be used in women of reproductive potential if indispensable, but their use should be accompanied by effective contraception. However, if conception occurs while on C5i or aFcRn, the risks of newborn immunosuppression must be weighed against the benefits on maternal disease control when considering the continuation of treatment.
 - IVIg and plasmapheresis can be used without restrictions in women of reproductive potential.
 - Thymectomy, even in the absence of suspected thymoma, is recommended in this age group (per criteria in 7.1.) and probably decreases the risk of neonatal MG. However, it should not be performed during pregnancy.

8.2. Precautions in the treatment of MG during pregnancy

- Regardless of the regular medication that the patient is taking, it should never be abruptly suspended at the time of pregnancy detection.
- Thymectomy should not be performed during pregnancy.
- Although the introduction of NSIs during pregnancy should be avoided, azathioprine is considered safe and can be maintained during this

period if it is considered important to maintain disease control.

- Magnesium sulfate should be avoided in the prophylaxis of eclampsia. If the patient develops eclampsia, namely with seizures, IV magnesium sulfate can be used although with extreme caution and with supervision by anesthesiology. Nonetheless, in the context of seizures, anti-seizure medications (e.g., levetiracetam) should preferably be used.

8.3. Childbirth issues

- Delivery and anesthetic approach should be planned.
- General anesthesia should be avoided but, if indispensable, neuromuscular blockers must not be used.
- In epidural anesthesia, drugs of the amide group (e.g., ropivacaine, bupivacaine) should preferably be used.
- Vaginal delivery should be the goal and should be actively encouraged. Cesarean section should be reserved for obstetric indications, including prolonged labor due to maternal exhaustion.
- Women with moderate or severe generalized MG near term may benefit from IVIg or plasmapheresis prior to delivery, to reduce the risk of worsening during labor and in the puerperium.
- Delivery should occur in a hospital with neonatology support and neonatal ICU, due to the risk of transient neonatal MG with possible need for ventilatory and nutritional support to the newborn.
- For the same reason, and because transient neonatal MG can develop a few hours or even days after delivery, the newborn should remain under observation for at least two days.

8.4. Breastfeeding issues

- Generally, breastfeeding should be encouraged among mothers with MG, as well as in the general population. However, in women receiving mycophenolate mofetil and methotrexate, breastfeeding should be discouraged.
- Treatments for MG that are considered safe during breastfeeding include: pyridostigmine, prednisolone, azathioprine, rituximab, IVIg, and plasmapheresis.

THERAPEUTIC ALGORITHMS

See Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24089/15824>)

15824).

CONCLUSION

To the best of our knowledge, these guidelines are the first to include formal diagnostic criteria for MG, designed to differentiate highly specific from non-specific clinical manifestations, and to clarify the role of ancillary diagnostic tools. They are also the first to provide detailed indications for the use of novel immunosuppressants in MG, together with comprehensive therapeutic algorithms tailored to serogroup and clinical severity. The working group believes that these recommendations will contribute to improving the care of patients with MG and to a greater consistency and standardization of concepts and of diagnostic and therapeutic strategies.

ACKNOWLEDGEMENTS

The authors would like to thank Joana Moniz Dionísio for designing the figures presented in this article.

The authors have declared that no AI tools were used during the preparation of this work.

AUTHOR CONTRIBUTIONS

SC: Literature review, writing of the manuscript.

AM: Literature review, writing and critical review of the manuscript.

LB, CFC, JC, LM, ES, LS, AV: Critical review of the manuscript.

All authors approved the final version to be published.

REFERENCES

1. Santos E, Coutinho E, Moreira I, Silva AM, Lopes D, Costa H, et al. Epidemiology of myasthenia gravis in Northern Portugal: frequency estimates and clinical epidemiological distribution of cases. *Muscle Nerve*. 2016;54:413-21.
2. Evoli A, Alboini PE, Damato V, Iorio R, Provenzano C, Bartoccioni E, et al. Myasthenia gravis with antibodies to MuSK: an update. *Ann N Y Acad Sci*. 2018;1412:82-9.
3. Gilhus NE, Tzartos S, Evoli A, Palace J, Burns TM, Verschuuren JJ. Myasthenia gravis. *Nat Rev Dis Primers*. 2019;5:30.
4. Gilhus NE, Andersen H, Andersen LK, Bolding M, Laakso S, Leopoldsdottir MO, et al. Generalized myasthenia gravis with acetylcholine receptor antibodies: a guidance for treatment. *Eur J Neurol*. 2024;31:e16229.
5. Wiendl H, Abicht A, Chan A, Della Marina A, Hagenacker T, Hekmat K, et al. Guideline for the management of myasthenic syndromes. *Ther Adv Neurol Disord*. 2023;16:17562864231213240.
6. Jacob S, Farrugia ME, Hewamadduma C, Norwood F, Hill M, Leite M, et al. Association of British Neurologists (ABN) autoimmune myasthenia gravis management guidelines (2025 update). *Pract Neurol*. 2025;25:422-37.
7. Evoli A, Antonini G, Antozzi C, DiMuzio A, Habetswallner F, Iani C, et al. Italian recommendations for the diagnosis and treatment of myasthenia gravis. *Neurol Sci*. 2019;40:1111-24.
8. Murai H, Utsugisawa K, Motomura M, Imai T, Uzawa A, Suzuki S. The Japanese clinical guidelines 2022 for myasthenia gravis and Lambert-Eaton myasthenic syndrome. *Clin Exp Neuroimmunol*. 2023;14:19-27.
9. Skeie GO, Apostolski S, Evoli A, Gilhus NE, Illa I, Harms L, et al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. *Eur J Neurol*. 2010;17:893-902.
10. Sanders DB, Wolfe GI, Benatar M, Evoli A, Gilhus NE, Illa I, et al. International consensus guidance for management of myasthenia gravis: executive summary. *Neurology*. 2016;87:419-25.
11. Narayanaswami P, Sanders DB, Wolfe G, Benatar M, Cea G, Evoli A, et al. International consensus guidance for management of myasthenia gravis: 2020 Update. *Neurology*. 2021;96:114-22.
12. Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR, Lázaro P, et al. The RAND/UCLA appropriateness method user's manual. [cited 2023 Sep 10]. Available from: rand.org/pubs/monograph_reports/MR1269.html.
13. Jaretzki A 3rd, Barohn RJ, Ernstoff RM, Kaminski HJ, Keesey JC, Penn AS, et al. Myasthenia gravis: recommendations for clinical research standards. Task Force of the Medical Scientific Advisory Board of the Myasthenia Gravis Foundation of America. *Neurology*. 2000;55:16-23.

CONFLICTS OF INTEREST

SC participated on advisory boards for Argenx and UCB Pharma; received speaker's honoraria from CSL Behring; performed medical writing for CSL Behring and Argenx; received support for attending meetings from CSL Behring, Kedrion and Takeda.

AM participated on advisory boards for Argenx and UCB Pharma.

LB participated on the advisory board for Argenx; performed medical writing for Argenx.

CFC acted as subinvestigator in a randomized controlled trial for Argenx; received speaker's honoraria from Argenx.

LM participated on advisory boards for Argenx and UCB Pharma; performed medical writing for argenx; received support for attending meetings from Argenx, CSL Behring and Kedrion.

ES received consulting fees from Alexion, Argenx, Takeda, and UCB; received speaker's honoraria from argenx; received support for attending meetings from Argenx.

All the other authors have no conflicts of interest to declare.

FUNDING SOURCES

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Aptidão Desportiva ou Aptidão Laboral? Um Debate Necessário

Sports Fitness or Occupational Fitness? A Necessary Debate

Palavras-chave: Aptidão Física; Medicina Desportiva; Medicina do Trabalho; Portugal

Keywords: Occupational Medicine; Physical Fitness; Portugal; Sports Medicine

Em Portugal, a Medicina do Trabalho e a Medicina Desportiva, embora distintas na sua génese, partilham os princípios transversais a todas as especialidades médicas de prevenção e promoção da saúde, com especial relevância na população ativa.

A Medicina Desportiva intervém tanto na avaliação da aptidão para a prática desportiva como na prevenção, diagnóstico e tratamento de lesões relacionadas com a mesma, acompanhando os atletas em contexto competitivo, inclusive de alto rendimento, assegurando a sua aptidão para um desempenho físico exigente. No entanto, importa refletir sobre uma realidade frequentemente negligenciada: sendo o desporto a profissão de muitos atletas, não deveriam estes ser igualmente abrangidos pela Medicina do Trabalho?

A Medicina do Trabalho atua em contexto laboral, com foco na vigilância da saúde dos trabalhadores, na prevenção de doenças profissionais, na identificação precoce de riscos profissionais e na adaptação das condições laborais às capacidades individuais, promovendo ambientes de trabalho saudáveis. Avalia, portanto, a aptidão para o exercício global da atividade, independentemente da natureza da mesma.^{1,2} No caso dos atletas, esta abordagem permitiria considerar dimensões que ultrapassam a condição físico-desportiva, como o impacto dos riscos psicossociais o stress e os horários praticados, as exigências ergonómicas e até aspetos relacionados com a longevidade da carreira e preparação para a reforma.³

Enquanto a Medicina Desportiva privilegia o desempenho e a prevenção de lesões no contexto desportivo, a Medicina do Trabalho oferece uma abordagem mais abrangente, com potencial para complementar com estratégias de reabilitação profissional, vigilância da saúde mental e planeamento de transição de carreira. A articulação entre

estas especialidades já foi destacada como oportunidade para desenvolver modelos integrados de intervenção em saúde.^{3,4}

Em alguns países têm-se explorado estes modelos, reconhecendo os atletas profissionais como indivíduos com direitos laborais e necessidades de saúde específicas.^{3,4} No contexto português, tal articulação não está formalmente estruturada, apesar do aumento da carreira profissional no desporto e da crescente sensibilização para os impactos ocupacionais desta atividade.

Torna-se, assim, pertinente, promover o debate sobre o desenvolvimento de modelos complementares de intervenção em saúde entre a Medicina Desportiva e a Medicina do Trabalho, com vista a uma maior proteção laboral e promoção de saúde ao longo da vida ativa dos desportistas profissionais. Integrar estas duas áreas não é apenas uma questão de eficiência clínica, mas um imperativo ético, garantindo que quem vive do desporto o faça com saúde, dignidade e segurança ao longo de todo o ciclo de vida ativo e laboral.

ACKNOWLEDGMENTS

Os autores declaram não ter utilizado ferramentas de inteligência artificial na elaboração do artigo.

CONTRIBUTO DOS AUTORES

MGL: Conceção do trabalho, recolha de dados, revisão crítica do manuscrito.

FOR, JPCB, JPSL: Análise e interpretação de dados, revisão crítica do manuscrito.

LP: Conceção do trabalho, análise e interpretação de dados, revisão crítica do manuscrito.

Todos os autores aprovaram a versão final a ser publicada.

CONFLITOS DE INTERESSE

Os autores declaram não ter conflitos de interesse relacionados com o presente trabalho.

FONTES DE FINANCIAMENTO

Este trabalho não recebeu qualquer tipo de suporte financeiro de nenhuma entidade no domínio público ou privado.

REFERÊNCIAS

1. Portugal. Decreto-Lei n.º 10/2009. Diário da República, I Série, n.º 7 (2009/01/12). p.220-4.
2. Portugal. Lei n.º 102/2009. Diário da República, I Série, n.º 176 (2009/09/10). p.6167-92.
3. Sánchez AR. Sports medicine vs occupational medicine: two divergent specialties with a common past. Arch Med Deporte. 2017;34:152-6.
4. Caine DJ. Sports and occupational medicine: two sides of the same coin? Occup Med. 2006;56:248-9.

Marta GRÁCIO LAGOA ¹, Flávio DE OLIVEIRA RIBEIRO ¹, João Pedro CARVALHO BARBOSA ¹, João Pedro DE SOUSA LIMA¹, Lisa PIRES ¹

1. Serviço de Medicina do Trabalho. Instituto Português de Oncologia do Porto Francisco Gentil. Porto. Portugal.

✉ Autor correspondente: Marta Grácio Lagoa. marta_lagoa10@hotmail.com

Recebido/Received: 12/08/2025 - Aceite/Accepted: 27/10/2025 - Publicado/Published: 02/01/2026

Copyright © Ordem dos Médicos 2026

<https://doi.org/10.20344/amp.23817>



Neoplasia Folicular Não Invasiva com Núcleos de Tipo Papilar em *Struma Ovarii*

Non-Invasive Follicular Neoplasm with Papillary-Like Nuclear Features in *Struma Ovarii*

Palavras-chave: Adenocarcinoma Follicular/diagnóstico; Carcinoma Papilar/diagnóstico *Struma Ovarii*/diagnóstico

Keywords: Adenocarcinoma, Follicular/diagnosis; Carcinoma, Papillary/diagnosis; *Struma Ovarii*/diagnosis

Struma ovarii é um tumor ovárico raro (0,3% - 1%), representando cerca de 5% dos teratomas maduros, caracterizado por conter pelo menos 50% de tecido tiroideu maduro.^{1,2} Pode ser benigno ou maligno (< 5%), sendo o diagnóstico histopatológico, devido aos achados clínicos e imagiológicos inespecíficos.¹ Em casos malignos, recomenda-se avaliação da glândula tiroideia para exclusão de tumor síncrono.² A abordagem ideal não é consensual, sendo indicada a discussão multidisciplinar, tendo em conta as características do doente e particularidades do tumor.²

A neoplasia folicular não invasiva com características nucleares de carcinoma papilar da tireóide (NIFTP), definida em 2016 e atualizada em 2022 com base em critérios histopatológicos, é caracterizada pela presença de uma neoplasia tiroideia bem delimitada de padrão folicular com aspetos nucleares de carcinoma papilar, sem invasão capsular ou vascular.³ Tendo um comportamento indolente e excelente prognóstico (sem mortalidade associada e taxa de recorrência inferior a 1%), o tratamento é geralmente conservador, com lobectomia isolada.⁴

Tanto quanto temos conhecimento, este é um dos primeiros casos descritos de NIFTP em *struma ovarii*. Trata-se de uma mulher saudável de 32 anos, caucasiana, nulípara,

com história familiar de neoplasia (carcinoma da mama em familiares de 1.º e 2.º graus, um dos quais com mutação *CHEK2*), proposta para cirurgia eletiva por lesão anexial direita complexa (ressonância magnética pélvica com evidência de lesão quística multiloculada com 82 x 66 x 80 mm, de paredes regulares e foco parietal sólido central de 15 mm com realce pelo contraste) com marcadores tumorais negativos. Foi submetida em contexto urgente a laparotomia por abdómen agudo, com evidência intraoperatória de torção anexial direita e realização de quistectomia.

O estudo anatomopatológico (Fig. 1) revelou *struma ovarii*, contendo um nódulo de 1 cm de epitélio folicular bem delimitado, com padrão microfolicular e alterações nucleares sugestivas de NIFTP. A avaliação tiroideia mostrou tiroidite sem alterações funcionais. O caso foi discutido em reunião multidisciplinar, optando-se por anexectomia direita devido ao risco de lesão do ovário remanescente, apesar do baixo potencial maligno.

O estudo genético confirmou a presença da variante familiar no gene *CHEK2* (c.319+2T>A). Essa mutação está associada ao aumento de risco para cancro da mama, colorretal e da próstata, pelo que a doente iniciou vigilância senológica adequada com ressonância magnética anual.⁵ A associação com o carcinoma da tireóide e rim ainda se encontra em investigação, sendo a evidência insuficiente no que diz respeito ao rastreio, com alguns autores a defender ecografia periódica de acordo com a história familiar.⁵

À data da redação do manuscrito, quatro anos após o diagnóstico de NIFTP, a doente encontra-se, em vigilância multidisciplinar, com estudo tiroideu anual (ecografia e avaliação analítica), assintomática e sem sinais de recidiva ou progressão da doença.

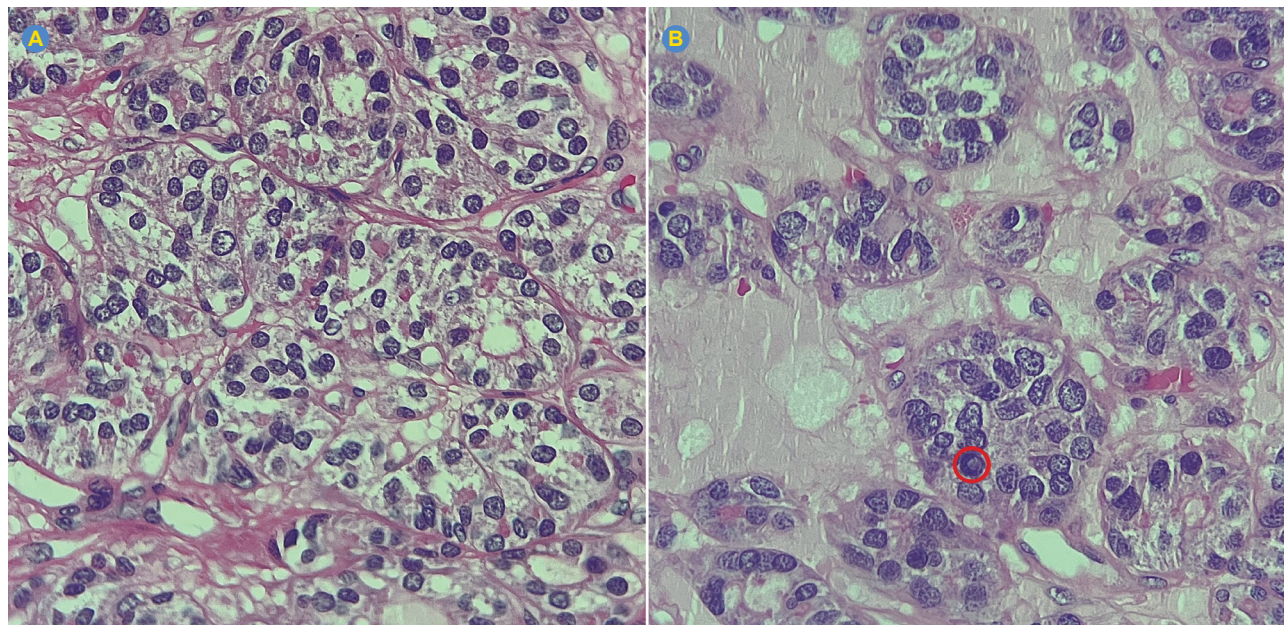


Figura 1 – (A) Coloração de hematoxilina-eosina (400x): células foliculares tumorais dispostas exclusivamente em padrão folicular e microfolicular, com núcleos globalmente de tamanho aumentado, alongados, de contornos irregulares, com moldagem e fendas nucleares, focalmente com clareamento da cromatina, identificando-se ainda raras pseudoinclusões nucleares (círculo vermelho em B)

ACKNOWLEDGMENTS

Os autores declaram não ter utilizado ferramentas de inteligência artificial na elaboração do artigo.

CONTRIBUTO DOS AUTORES

SSA: Redação e revisão crítica do manuscrito.

CL, VS, TDC, ASO, CM, JT, LG: Revisão crítica do manuscrito.

Todos os autores aprovaram a versão final a ser publicada.

PROTEÇÃO DE PESSOAS E ANIMAIS

Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pelos responsáveis da Comissão de Investigação Clínica e Ética e de acordo com a Declaração de Helsínquia da Associação Médica Mundial atualizada em outubro de 2024.

REFERÊNCIAS

1. Ross D. Struma ovarii. Uptodate. 2025. [consultado 2024 ago 08]. Disponível em: https://www.uptodate.com/contents/struma-ovarii?search=struma%20ovarii&source=search_result&selectedTitle=1~6&usage_type=default&display_rank=1.
2. Smith L, Brubaker L, Wolksky R. It does exist! Diagnosis and management of thyroid carcinomas originating in struma ovarii. Surg Pathol. 2023;16:75-86.
3. Jung C, Bychkov A, Kakudo K. Update from the 2022 World Health Organization Classification of thyroid tumors: a standardized diagnostic

CONFIDENCIALIDADE DOS DADOS

Os autores declaram ter seguido os protocolos do seu centro de trabalho acerca da publicação de dados.

CONSENTIMENTO DO DOENTE

Obtido.

CONFLITOS DE INTERESSE

Os autores declaram não ter conflitos de interesse relacionados com o presente trabalho.

FONTES DE FINANCIAMENTO

Este trabalho não recebeu qualquer tipo de suporte financeiro de nenhuma entidade no domínio público ou privado.

4. approach. Endocrinol Metab. 2022;37:703-18.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology (NCCN Guidelines®) - Thyroid Carcinoma, Version 3.2023. Plymouth Meeting: NCCN; 2023.
5. Graffeo R, Rana HQ, Conforti F, Bonanni B, Cardoso MJ, Paluch-Shimon S, et al. Moderate penetrance genes complicate genetic testing for breast cancer diagnosis: ATM, CHEK2, BARD1 and RAD51D. Breast. 2022;65:32-40.

Sara SARDINHA ABRANTES¹, Cláudia LOPES², Vanessa SANTOS¹, Teresa DINIZ COSTA¹, Ana Sofia OSÓRIO³, Catarina MACHADO⁴, Joaquim TINOCO⁵, Lucília GONÇALVES⁵

1. Serviço de Ginecologia. Hospital Prof. Doutor Fernando Fonseca. Amadora. Portugal.

2. Serviço de Ginecologia. Centro Hospitalar Barreiro-Montijo. Barreiro. Portugal.

3. Serviço de Endocrinologia. Hospital Prof. Doutor Fernando Fonseca. Amadora. Portugal.

4. Serviço de Genética Médica. Hospital Prof. Doutor Fernando Fonseca. Amadora. Portugal.

5. Serviço de Anatomia Patológica. Hospital Prof. Doutor Fernando Fonseca. Amadora. Portugal.

✉ Autor correspondente: Sara Sardinha Abrantes. sara.sardinha.abrantes@gmail.com

Recebido/Received: 08/09/2025 - Aceite/Accepted: 27/10/2025 - Publicado/Published: 02/01/2026

Copyright © Ordem dos Médicos 2026

<https://doi.org/10.20344/amp.23942>



Liberal Health Professions in the European Union: Concepts, Ethics, and a Call for Harmonization

Profissões Liberais de Saúde na União Europeia: Conceitos, Ética e um Apelo à Harmonização

Keywords: Europe; Health Personnel/ethics
Palavras-chave: Europa; Pessoal de Saúde/ética

There is a longstanding tradition of autonomy, independence, and socially valued regulation in the organization of the liberal professions, a tradition that has continuously evolved to the present day. The values that inspire liberal professions can only be upheld in free and democratic societies that respect and protect their autonomy.^{1,2}

The report “The State of Liberal Professions Concerning their Functions and Relevance to European Civil Society”¹ notes that, “historically, according to Cicero and Seneca, these were activities worthy of a free person, and their learning was indeed a necessity for every free Roman citizen. The practice of the *artes liberales* was therefore a privilege of free citizens.”

The modern understanding of the concept of the 'liberal profession' has fortunately evolved. Until the eighteenth century, the term '*artes liberales*' continued to refer to 'intellectual' activities.³ At that point, the term ceased to denote the personal attribute of 'free birth' and became associated instead with the professional activity itself. Since the time of Hippocrates, health professions – particularly medical ones – have embraced a set of principles rooted in values that have continually evolved. At one of its earliest meetings, held in Philadelphia (1847), the American Medical Association (AMA) adopted a resolution on medical ethics, inspired by an earlier work written by Thomas Percival. One of the themes that began to emerge in Percival's code, and later gained prominence in the AMA's code – is the tension between a physician's duty to the individual patient and the broader obligations owed to society.⁴ Across the European Union, the liberal professions in member states are characterized by two fundamental dimensions: their collective

REFERENCES

1. European Economic and Social Committee, Ulmer K, Moll N, Dorando T, Hesse C, Arentz O, et al. The state of liberal professions concerning their functions and relevance to European civil society. Brussels: European Economic and Social Committee; 2014.
2. European Union. Communication from the commission - report on competition in professional services /* COM/2004/0083 final. [cited 2025 Jan 26]. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX%3A52004DC0083>.
3. Costa Nunes RA. As artes liberais na idade média. *Revista História*.

organization and, deriving from it, a well-established tradition of self-regulation.⁵

According to the Rome Manifesto (2017),⁶ adopted by the European Economic and Social Committee (EESC), "(...) Liberal professions involve the provision of intellectual services grounded in specific qualifications or professional training. These services are distinguished by a personal dimension and are built upon a foundation of trust. Liberal professionals carry out their activities with personal responsibility and professional independence, guided by ethical standards, committed to serving both their clients' interests and the common good, and operating within a structured system of professional organization and oversight. This definition is not exhaustive but remains open to new technological developments and new professions."

Liberal professions are characterized by varying degrees of autonomy and independence, as well as by adherence to their own ethical and deontological codes. These principles are expressed through a set of duties aimed at fostering public trust among consumers and citizens alike, thereby affirming the public-interest nature of professional self-regulation.

As these values, principles, and duties continue to be fragmented across multiple frameworks, it becomes imperative to consolidate and systematize them, encouraging thoughtful consideration of their alignment and effective implementation throughout Europe.

ACKNOWLEDGMENTS

The author has declared that no AI tools were used during the preparation of this work.

CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

FUNDING SOURCES

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

1975;26:3-23.

4. Veatch RM. Cross-cultural perspectives in medical ethics. Boston: Jones and Bartlett; 2000.
5. Wendt IE. EU competition law and liberal professions: an uneasy relationship? Rotterdam: Martinus Nijhoff Publishers; 2012.
6. European Economic and Social Committee. Manifesto: Definitions of the concept of liberal profession at European level. [cited 2024 Dez 04]. Available from: <https://www.eesc.europa.eu/en/documents/manifesto-definitions-concept-liberal-profession-european-level>.

Orlando José MENDES MONTEIRO DA SILVA 1

1. Faculdade de Medicina, Universidade do Porto, Porto, Portugal.

✉ **Autor correspondente:** Orlando José Mendes Monteiro da Silva. orlando@orlando.pt

Recebido/Received: 03/11/2025 - Aceite/Accepted: 04/11/2025 - Publicado Online/Published Online: 09/12/2025 - Publicado/Published: 02/01/2026

Copyright © Ordem dos Médicos 2026

<https://doi.org/10.20344/amp.24185>



Internar Involuntariamente ou Não Internar? A Dúvida na Ideação Suicida

To Admit Involuntarily or Not? The Dilemma in Suicidal Ideation

Palavras-chave: Ideação Suicida; Internamento Involuntário; Internamento de Pessoas com Perturbações Psiquiátricas; Prevenção do Suicídio; Saúde Mental/legislação e jurisprudência

Keywords: Commitment of Persons with Psychiatric Disorders; Involuntary Commitment; Mental Health/legislation & jurisprudence; Suicidal Ideation; Suicide Prevention

O suicídio é definido como “o ato deliberado e intencional levado a cabo para pôr termo à própria vida”.¹ Apesar de ser considerado raro,¹ é comum depararmo-nos com ideação suicida (IS) na atividade profissional. E, se a aplicação da Lei de Saúde Mental (LSM) é inequívoca perante psicoses e episódios maníacos, o mesmo não se verifica nos quadros clínicos com IS.²

Desde a criminalização à condenação moral, as abordagens legais e políticas relativas ao suicídio têm evoluído, focando-se atualmente na consciencialização, prevenção e apoio. Exemplos deste progresso são os manuais *Preventing Suicide: A Global Imperative*³ e o *Manual de Prevenção de Suicídio para Profissionais de Saúde*,¹ que destacam a importância da intervenção precoce e da capacitação profissional. Contudo, estes manuais não mencionam o papel do internamento involuntário (II) no doente com IS, remetendo esta decisão para cada país.^{4,5}

Em Portugal, o II é um instrumento jurídico e clínico disponível para situações de doença mental.² A nova LSM revê o regime do II, prevendo que este apenas possa ocorrer mediante decisão judicial, nas situações contempladas na Fig. 1.²

Coloca-se então o dilema: será a IS estruturada, per-

sistente e resistente à intervenção, suficiente para justificar um II?

Suponha-se o caso de um paciente com IS estruturada, sem rede de suporte e com acesso a meios letais; apesar da nossa intervenção em crise, o doente não consegue visualizar outra alternativa de vida, recusando o tratamento/internamento. Neste momento confrontamo-nos com um conflito clínico, ético e legal, que emerge da tensão entre a manutenção da autonomia e o dever de proteção: internar involuntariamente ou não internar? Terá este doente o discernimento necessário para avaliar o sentido e alcance do seu consentimento?

De facto, como medida preventiva do suicídio, o II é plausível em muitos países, como a Inglaterra e o País de Gales, sendo até considerada negligência médica ou indiligência aos direitos humanos quando não cumprida.⁵ Em Portugal, embora a nova LSM modernize e reforce os direitos, a sua aplicação às doenças com IS continua ambígua, pela subjetividade dos critérios realçados na Fig. 1, conduzindo a decisões díspares entre profissionais.

Esta indefinição legal e a ausência de normas específicas para a atuação em casos de IS deixam os profissionais de saúde mental numa zona cinzenta, onde o julgamento clínico individual é determinante, mas vulnerável. Torna-se necessária uma clarificação adicional – quer jurídica, quer clínica – que permita uniformizar critérios, proteger os doentes em risco e apoiar os profissionais na sua atuação.

ACKNOWLEDGMENTS

Os autores declaram não ter utilizado ferramentas de inteligência artificial na elaboração do artigo.

CONTRIBUTO DOS AUTORES

JC: Pesquisa bibliográfica e elaboração do manuscrito.

Artigo 15.º

Pressupostos e princípios gerais

1 – São pressupostos cumulativos do tratamento involuntário:

- a) A existência de doença mental;
- b) A recusa do tratamento medicamente prescrito, necessário para prevenir ou eliminar o perigo previsto na alínea seguinte;
- c) A existência de perigo para bens jurídicos pessoais ou patrimoniais:
 - i) De terceiros, em razão da doença mental e da recusa de tratamento; ou
 - ii) Do próprio, em razão da doença mental e da recusa de tratamento, quando a pessoa não possua o discernimento necessário para avaliar o sentido e alcance do consentimento;
- d) A finalidade do tratamento, conforme previsto no artigo anterior.

2 – O tratamento involuntário só pode ter lugar se for:

- a) A única forma de garantir o tratamento medicamente prescrito;
- b) Adequado para prevenir ou eliminar uma das situações de perigo previstas na alínea c) do número anterior; e
- c) Proporcional à gravidade da doença mental, ao grau de perigo e à relevância do bem jurídico.

3 – O tratamento involuntário tem lugar em ambulatório, assegurado por equipas comunitárias de saúde mental, exceto se o internamento for a única forma de garantir o tratamento medicamente prescrito, cessando logo que o tratamento possa ser retomado em ambulatório.

4 – As restrições aos direitos, vontade e preferências das pessoas com necessidades de cuidados de saúde mental decorrentes do tratamento involuntário são estritamente necessárias e adequadas à efetividade do tratamento, à segurança e à normalidade do funcionamento da unidade de internamento do serviço local ou regional de saúde mental, nos termos do respetivo regulamento interno.

Figura 1 – Pressupostos e princípios gerais na LSM²

MC, SM, RC: Revisão crítica do manuscrito.

Todos os autores aprovaram a versão final a ser publicada.

CONFLITOS DE INTERESSE

JC recebeu apoio para participação em reuniões e/ou viagens de Rovi, Angelini Pharma, Bial, Alter Médica e Jaba Recordatti.

MC recebeu apoio para participação em reuniões e/ou viagens de Janssen, Tecnifar, Jaba Recordati e Bial.

SM recebeu apoio para participação em reuniões e/ou viagens de Angelini Pharma, Bial e Jaba Recordatti.

RC recebeu apoio para participação em reuniões e/ou viagens de Mylan e Angelini Pharma.

FONTES DE FINANCIAMENTO

Este trabalho não recebeu qualquer tipo de suporte financeiro de nenhuma entidade no domínio público ou privado.

REFERÊNCIAS

1. Barbosa P, Silva SF, Madeira N, Pires AM, Valadas MT, Freitas RM, et al. Prevenção do suicídio: manual para profissionais de saúde. Moura: ARIS da Planície; 2021.
2. Portugal. Lei n.º 35/2023. Diário da República, I Série, n.º 141 (2023/07/21), p. 2-23.
3. World Health Organization. Preventing suicide: a global imperative. Geneva: WHO; 2014.
4. Wang DW, Colucci E. Should compulsory admission to hospital be part of suicide prevention strategies? BJPsych Bull. 2017;41:169-71.
5. Wasserman D, Apter G, Baeken C, Bailey S, Balazs J, Bec C, et al. Compulsory admissions of patients with mental disorders: state of the art on ethical and legislative aspects in 40 European countries. Eur Psychiatry. 2020;63:e82.

Joana CARDÃO ¹, Cláudia Marina CRUZ ², Salomé MOUTA ³, Rafael SILVA CARVALHO ⁴

1. Serviço de Psiquiatria. Departamento de Psiquiatria e Saúde Mental. Unidade Local de Saúde do Alto Alentejo. Portalegre. Portugal.

2. Serviço de Psiquiatria. Hospital do Divino Espírito Santo de Ponta Delgada. Ponta Del. Portugal.

3. Serviço de Psiquiatria. Departamento de Psiquiatria e Saúde Mental. Unidade Local de Saúde da Guarda. Guarda. Portugal.

4. Serviço de Psiquiatria de Agudos e de Apoio à Urgência Metropolitana. Departamento de Saúde Mental. Hospital de Magalhães Lemos. Unidade Local de Saúde de Santo António. Porto. Portugal.

✉ Autor correspondente: Joana Cardão. joanacardao17@gmail.com

Revisto por/Reviewed by: Carolina Rocha Almeida.

Recebido/Received: 22/07/2025 - Aceite/Accepted: 26/11/2025 - Publicado/Published: 02/01/2026

Copyright © Ordem dos Médicos 2026

<https://doi.org/10.20344/amp.23717>





PubMed



LinkedIn

www.actamedicaportuguesa.com