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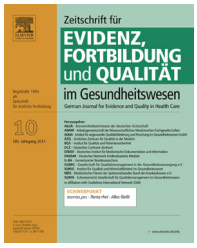

WISSENSCHAFTLICHER BEITRAG

# Health technology assessment of medical devices: What is different? An overview of three European projects

## *Health Technology Assessment von Medizinprodukten: Was ist anders? Eine Übersicht über drei europäische Projekte*

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**Summary**
**Background:** With the growing use and importance of health technology assessment (HTA) in decision making during recent years, health technology assessors, decision makers and stakeholders are confronted with methodological challenges due to specific characteristics of health technologies (e. g., pharmaceuticals, diagnostic tests, screening programs), their developmental environment, and their regulation process. Being aware of the necessity to use HTA as a policy instrument for sustainable health care systems in a regulatory environment of decentralized Conformité Européenne (CE) marking, the European Union (EU) is increasingly supporting the development of methods for the assessment of medical devices (MD) on different levels: within the scope of European research projects and within joint assessment activities of the member states of the *European network for Health Technology Assessment* (EUnetHTA).
**Objective:** First, this article describes three projects: MedtecHTA—Methods for Health Technology Assessment of Medical Devices, a European Perspective Work Package 3 (WP3), Comparative Effectiveness of Medical Devices led by the University for Health Sciences, Medical Informatics and Technology (UMIT). Second, we discuss the experiences of the Ludwig Boltzmann

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Institute Health Technology Assessment (LBI HTA) with the joint production of rapid assessments of medical devices by several European HTA agencies within EUnetHTA. Third, a brief outline is given of the framework of joint methodological guideline elaboration by the EUnetHTA partner organizations because a guideline for therapeutic MD is also being developed here.

**Methods:** We will describe aims, methods and some preliminary results of MedtecHTA and EUnetHTA Joint Action 2 Work Package 5 Strand B (WP5B) applying the HTA Core Model for Rapid Assessment for national adaptation and reporting, and give an overview of the development process of methodological guidelines within WP 7 of EUnetHTA Joint Action 2.

**Results:** Based on a literature review in MedtecHTA WP3 incremental development, context dependency and the physical mode of action of MD were identified as those characteristics making therapeutic MD different from drugs with regard to evaluation methods. In addition, regulation does not stipulate clinical trials.

These characteristics were also identified as challenges for the production of joint assessments of MD within the HTA network EUnetHTA. Furthermore, adequate timing of assessment production, the variety of involved manufacturers, the non-transparent regulation process of MD in Europe and the often poor evidence base pose a challenge to EUnetHTA assessors. As a consequence, processes and methods for the joint production of rapid assessments must be continuously adapted and improved.

**Discussion:** Research on HTA methods for the assessment of MD tries to provide tools to deal with rapidly developing devices during evidence generation, dependence of clinical effectiveness of MD on user experience and context factors. There are also tools to integrate evidence from different sources adjusting for different levels of validity, but these methods are not established and need high epidemiological and statistical expertise. A framework for deciding whether additional evidence is needed to reduce uncertainty regarding safety, clinical effectiveness and cost-effectiveness will be adapted to MD. The whole process of evidence generation before and after market access has to be considered to provide an environment for conclusive HTA recommendations informing health care decision making. In Joint Action 2, EUnetHTA develops transparent processes for the early dialogue with stakeholders and fosters dissemination of appropriate HTA methods. In the case of MD, there are special accumulated needs for such efforts.

**SCHLÜSSELWÖRTER**
Technikbewertung;
Medizinprodukte;
internationale
Kooperation

**Zusammenfassung**

**Hintergrund:** Mit der in den letzten Jahren zunehmenden Anwendung und Bedeutung von Health Technology Assessment (HTA) für die Entscheidungsfindung werden Gutachter, Entscheidungsträger und Interessenvertreter mit methodischen Herausforderungen konfrontiert, die sich aus den spezifischen Eigenschaften der Technologien (z. B. Medikamente, diagnostische Tests, Früherkennungsprogramme), ihrem Entwicklungsumfeld und ihrem Regulationsprozess ergeben. Angesichts der Notwendigkeit, HTA als strategisches Instrument für nachhaltige Gesundheitssysteme in einem regulatorischen Umfeld mit dezentralisierter Conformité-Européenne-(CE-)Zertifizierung einzusetzen, unterstützt die Europäische Union (EU) zunehmend die Methodenentwicklung für die Bewertung von Medizinprodukten (MP) auf unterschiedlichen Ebenen: innerhalb von europäischen Forschungsprojekten und in gemeinsamen Technologiebewertungen von Mitgliedsstaaten des *European network for HTA* (EUnetHTA).

**Zielsetzung:** Dieser Artikel beschreibt erstens drei Projekte zu HTA von MP: MedtecHTA—Methods for Health Technology Assessment of Medical Devices, a European Perspective, Work Package 3 (WP3), Comparative Effectiveness of Medical Devices, geleitet von der Universität für Gesundheitswissenschaften, Medizinische Informatik und Technik (UMIT). Zweitens diskutieren wir die Erfahrungen des Ludwig Boltzmann Instituts für Health Technology Assessment (LBI HTA) mit der gemeinschaftlichen Erstellung von Kurzbewertungen von MP mehrerer europäischer HTA-Agenturen innerhalb von EUnetHTA. Drittens wird ein kurzer Abriss über den konzeptionellen Rahmen der gemeinsamen Ausarbeitung von Methodenleitlinien durch EUnetHTA-Partnerorganisationen gegeben, da hier ebenfalls eine Leitlinie zu therapeutischen MP entwickelt wird.

**Methoden:** Wir beschreiben Ziele, Methoden und einige vorläufige Ergebnisse von MedtecHTA und EUnetHTA Joint Action 2 Arbeitspaket 5 Teil B (WP5B) „Applying the HTA core model for rapid assessment for national adaptation and reporting“, und geben einen Überblick über den Entwicklungsprozess der Methodenleitlinien im WP 7 der EunetHTA Joint Action 2.

**Ergebnisse:** Basierend auf einer Literaturübersicht aus MedtecHTA WP3 wurden die inkrementelle Entwicklung, die Kontextabhängigkeit und der physikalische Wirkmechanismus von MP als jene Eigenschaften identifiziert, die MP im Hinblick auf Bewertungsmethoden von Arzneimitteln unterscheiden. Zudem sind in der Zulassung klinische Studien nicht vorgeschrieben.

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