

**Authors:**

Dr. Aidatul Azura Abdul Rani  
Dr. Ahmad Tasnim Muslim

**Information Specialist:**

Zamilah Mat Jusoh@Yusof

**Reviewer (HTA Expert):**

Dr. Izzuna Mudla Mohamed Ghazali

**External Reviewer:**

Dr. Ngu Lock Hock

**Disclaimer:**

This Health Technology Assessment has been developed from analysis, interpretation and synthesis of scientific research and/or technology assessment conducted by other organizations. It also incorporates, where available, Malaysian data, and information provided by experts to the Ministry of Health Malaysia. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of the review.

For further information please contact:

Malaysian Health Technology  
Assessment Section (MaHTAS)  
Medical Development Division  
Ministry of Health Malaysia  
Level 4, Block E1, Precinct 1  
Government Office Complex  
62590 Putrajaya.

Tel: 603 8883 1229

Available at the following website:  
<http://www.moh.gov.my>

2024

**Background**

The genomics field has advanced rapidly since the human genome was mapped, leading to significant progress in epigenetics. Epigenetics studies heritable changes in gene expression influenced by external factors, without altering the DNA sequence. Key mechanisms—DNA methylation, histone modification, and non-coding RNA molecules—play key roles in regulating gene expression during development and in response to environmental factors such as diet, stress, and exposure to pollutants. DNA methylation, a primary epigenetic process, controls gene activity by adding methyl groups to DNA. It is essential for normal development but can also contribute to diseases like cancer when abnormal patterns occur. Histone modifications and non-coding RNAs also regulate gene expression and have been linked to conditions such as neurodegenerative and cardiovascular diseases.

Epigenetics has practical applications in healthcare, as it shows how lifestyle and environmental factors can influence gene expression. For example, nutrients like folate and vitamin B12 affect DNA methylation, and physical exercise can influence epigenetic changes in various tissues. This knowledge helps guide preventive healthcare strategies and improve health outcomes. Epigenetic clocks based on DNA methylation patterns have been developed to estimate biological age, which is a better predictor of age-related diseases than chronological age. Earlier clocks like Horvath and Hannum were designed to estimate chronological age. Newer models, such as PhenoAge and GrimAge, provide insights into disease risk and mortality, helping to personalise healthcare.

In light of these advances, a new health screening procedure has emerged utilising a portable device, which analyses hair samples. This assessment was prepared in response to a request by the Director of Medical Practice Division, Ministry of Health Malaysia, to provide comprehensive information on the effectiveness and recognition of this procedure in clinical practice.

**Objective:**

- i. To evaluate the effectiveness of epigenetic hair analysis in predicting health status in healthy adults.
- ii. To assess the safety aspects of epigenetic hair analysis and epigenetic testing.
- iii. To examine the economic, social, ethical, and organisational implications related to epigenetic testing.

**Results:**

**Search results**

A total of **1,631** records were identified through the Ovid and PubMed, with **10** more from other sources. After removing duplicates, **1,631** titles were screened using inclusion and exclusion criteria, leading to **24** relevant abstracts that were retrieved in full text. Of these, **nine** full-text articles were selected, including **one** systematic review, **one** scoping review, **one** randomised controlled trial, **two** cohort studies, **one** pilot study, and **three** in-vitro studies. All the included studies were published in English between 2012 and 2023, with the majority conducted in the United States of America (five studies). Additionally,

one study each was conducted in the United Kingdom, France, Germany, and China.

### **Effectiveness**

From the systematic review, the outcomes were categorised as follows:

#### **1. Hair Follicles and Signature Wave Technology**

- There was no retrievable evidence on the hair follicles analysis utilising wave resonance and vibrational analysis to decode epigenetic information.

#### **2. Hair Follicles and DNA methylation**

Three in-vitro studies analysed the anagen phase of hair follicles using DNA methylation techniques, yielding the following results:

- Individuals with the 5-HTTLPR S/S genotype and low SLC6A4 methylation had higher hair cortisol levels ( $\beta=0.83$ ,  $p=0.049$ ), indicating increased sensitivity to stress.
- DNAm methylation of scalp hair follicles can predict age, with a mean absolute deviation (MAD) of 3.68 years.
- Hair follicles-derived induced pluripotent stem-cells (HF-iPSCs) demonstrated differentiation into the three embryonic germ layers and neuronal cells, offering potential for neurodevelopmental disorder research.

#### **3. DNA methylation as a blood-based biomarker in assessing wellbeing**

DNA methylation analysis is emerging as a valuable tool in understanding how various factors, such as social determinants and lifestyle, influence biological aging and wellbeing.

Methylation patterns influenced by social determinants like trauma and socioeconomic status can reflect biological aging, with neighbourhood environment impacting epigenetic age. Positive factors like greenness slow aging, while negative ones accelerate it. Lifestyle interventions, such as diet and exercise, alter DNA methylation linked to immunity, tumour suppression, and ageing. Epigenetic clocks like GrimAge and DunedinPoAm predict disease risks for COPD, diabetes, heart disease, and mortality. Higher cardiovascular health scores and lower GrimAge acceleration associated with reduced risk for cardiovascular disease and cognitive decline.

### **Safety**

There was no retrievable evidence on the adverse events or complications related to the use of the portable device or the sample collection process for analysis. The procedure is non-invasive, using hair plucking, and generally considered low-risk.

### **Organisational**

The device is easy to use in clinical settings but raises concerns about data privacy and security. Organisations need strong cybersecurity measures to protect personal health data and comply with data protection laws.

**Economic implication**

No evidence on cost-effectiveness is available. The device itself priced between USD 3,500 and USD 4,000 depending on the provider.

**Legal**

The reviewed device has several international certifications: Conformité Européenne (CE) mark, Electrical Testing Laboratories (ETL), Federal Communications Commission (FCC) approval, and China Quality Certification (CQC), but it is not registered as a medical device in Malaysia.

**Conclusion**

Epigenetic modifications, particularly DNA methylation, are a valuable tool for understanding the relationship between environmental factors, aging, and disease risk. Most current studies primarily analyse DNA samples from peripheral blood, buccal swabs, and saliva. Research on DNA methylation from hair follicles remains limited, with **no evidence supporting the use of wave resonance and vibrational analysis for decoding epigenetic information**. The epigenetic signatures associated with human wellbeing have not been scientifically established for routine use in risk prediction, prognosis, or diagnosis beyond the scope of research. It should not be used for profit-driven initiatives until its scientific use is well proven. Epigenetic profiles are highly cell-type specific. Analysing only the hair follicle cells is unlikely to be a representative epigenetic profile for an individual.

**Methods**

Electronic databases were searched through the Ovid interface: Ovid MEDLINE® ALL 1946 to June 28, 2024, EBM Reviews - Cochrane Central Register of Controlled Trials June 2024, EBM Reviews - Database of Abstracts of Reviews of Effects - 1st Quarter 2016, EBM Reviews - Cochrane Database of Systematic Reviews 2005 to June 28, 2024, EBM Reviews - Health Technology Assessment 4th Quarter 2016, EBM Reviews - NHS Economic Evaluation Database 1st Quarter 2016. Searches were also run in Pubmed, US FDA and INAHTA websites. Google was used to search for additional web-based materials and information. The search was limited to articles on human. There was no language limitation in the search. Additional articles were identified from reviewing the references and bibliographies of the retrieved articles. The last search was conducted on 28th June 2024.