Integration of a Personalized Health Care Model within Health Care Systems and Policies in Europe

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Outline

• Introduction
• Structure of the thesis
• Overview of the chapters and main results
• Main conclusions
Outline

• Introduction
  – Conceptual background
  – A practice model for personalized health care: Gentest
  – Aim

• Structure of the thesis

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Burden of Chronic Complex Diseases

• Health care is in crisis due to burden of chronic complex diseases.
• Cardiovascular diseases, cancers, diabetes, chronic respiratory diseases, and osteoporosis ...
• They are number one killers:
  – 9 people out of 10 die of a chronic disease in Europe
• They are common, chronic and costly.
  – Responsible for 80% of all health care costs in Europe = 700 billion Euros annually in Europe, and increasing every year!
• Population is aging rapidly in Europe.
• There is an urgent need for innovative approaches to effectively prevent chronic conditions to tackle this challenge.
• Use of genome-based information and personalized approaches to medicine and health care practices might provide opportunities.
Determinants of health

- Biological
- Socio-economic
- Health systems
- Life style & environ.
Genetic structure

Diseases related to external factors

Infectious diseases

Chronic complex diseases

1% of burden of disease*

10% of burden of disease*

3% of burden of disease*

86% of burden of disease*

Disease threshold

Genetic diseases

Diseases related to external factors

Infectious diseases

Chronic complex diseases

Lifestyle & environment

Pathogens

External factors

Genetic structure

Phylogeny Development

Phase I

Disease threshold

Early signs threshold

Pathology Development

Phase I

Genetic predisposition

Lifestyle and environmental conditions

Check-up & Early Diagnosis

Diagnosis & Treatment

Early Signs Phase II

Disease Phase III

Conception

Death
Outline

• **Introduction**
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• Main conclusions
• GENAR Institute for Public Health and Genomics Research was established in Hacettepe University Science Park, Ankara, Turkey in 2004.

• As an endeavor to face the challenge of chronic complex diseases, GENAR developed Gentest as an integrative preventive model for prevention of complex diseases in primary care settings.
• Gentest was identified as a ‘best practice model in Europe’ by Public Health Genomics European Network (PHGEN) in 2008.

• It was implemented on more than 500 individuals in Turkey as a pilot via authorized practitioners (doctors) (authorized after a training by Turkish Society of Public Health Genomics and Personalized Medicine – TOGEN)
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  – Aim

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Aim of the thesis

• To explore how a personalized health care model, such as Gentest, can be integrated in primary care services in European health care systems, for prevention of complex diseases.
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• **Structure of the thesis**
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Integration of a Personalized Health Care Model within Health Care Systems and Policies in Europe

Where to integrate?
- A framework for public health and health systems interrelations: Health Globe
- Looking at US Health System from European Perspective

How to integrate?
- A systematic approach to assess integration of Gentest into primary care services

What to integrate?
- A perspective on personalized health care
- Introducing the practice model: Gentest
- Debating the definition of personalized approaches: Content analysis of practices
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How to integrate?
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There is a confusion around concepts of public health, including health system and its components, and how these are related to each other. Related concepts have been defined in separate contexts. There is a need for an integrated coherent framework.
Health Globe

- Health for All paradigm of World Health Organization
- Everything that relates to a society’s (and its individuals) health is a part of public health:
  - Medical and non-medical interventions (personal or population based health services)
  - Governmental decisions and practices
  - Activities of the public sector, private sector and NGOs
- Health system is component of it.

* Objective of World Health Organization as described in its Constitution.
Health System Pyramid

- Functions of a health system:
  - Stewardship
  - Health services
  - Financing
  - Resource generation
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How to integrate?
A systematic approach to assess integration of Gentest into primary care services
A look at health care ‘system’ in USA

- Serious shortcomings:
  - Ineffectiveness
  - Inefficiency
  - Inequity

- Underlying problem is the policy values:
  - Prioritizing freedom (i.e. free market) over ‘equity’

- Proposed how to develop an American Health System, from a European perspective
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A perspective on personalized health care

“Public health perspective: from personalized medicine to personal health”

- The shift from ‘one-size-fits-all’ towards personalized interventions
- Drivers:
  - General societal trend towards personalization
  - Rapid developments in genome-based science and technologies and information and communication technologies
- A perspective on the differences of commonly used terms in the field
  - Personalized medicine – stratification
  - Individualized medicine – computer modelling
  - Personalized health care – not just medicine but the full breadth of health services
- It’s not just genes that make individuals unique; it is the whole determinants of health that can be used to ‘personalize’ health and health care.
How to integrate?

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Debating the definition of personalized approaches: Content analysis of practices

Looking at US Health System from European Perspective

A systematic approach to assess integration of Gentest into primary care services.
Diabetes risk in 10 years: % 25
Heart attack risk in 10 years: % 21
Lung Cancer Risk

High

Average

Low

Reference
# Medical Follow-up Plan

## MEDICAL FOLLOW-UP PLAN

<table>
<thead>
<tr>
<th></th>
<th>M0</th>
<th>M1</th>
<th>M2</th>
<th>M3</th>
<th>M6</th>
<th>M9</th>
<th>M12</th>
<th>Y2</th>
<th>Y3</th>
<th>Y4</th>
<th>Y5</th>
<th>Follow-up period</th>
<th>Note</th>
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<tbody>
<tr>
<td><strong>DIABETES</strong></td>
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<tr>
<td>Fasting plasma glucose</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>Repeat test every 6 months</td>
<td>Will be identified based on the initial results.</td>
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<tr>
<td>OGTT</td>
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<td>Fasting insulin</td>
<td>X</td>
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<td><strong>CARDIOVASCULAR AND CEREBROVASCULAR HEALTH</strong></td>
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<tr>
<td>Blood pressure</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>4 X</td>
<td>4 X</td>
<td>4 X</td>
<td>4 X</td>
<td>4 X</td>
<td>4 X</td>
<td>Repeat measurement every 3 months</td>
<td>If values are higher than 120/80 mmHg, consult your physician.</td>
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<tr>
<td>LDL cholesterol</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>Repeat test every 6 months</td>
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<tr>
<td>HDL cholesterol</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>2 X</td>
<td>2 X</td>
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<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>Repeat test every 6 months</td>
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<tr>
<td>Total cholesterol</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>2 X</td>
<td>2 X</td>
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<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>Repeat test every 6 months</td>
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<tr>
<td>Triglyceride</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>Repeat test every 6 months</td>
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<tr>
<td>Homocysteine</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>Repeat test every 6 months</td>
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<tr>
<td>hs-CRP</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>2 X</td>
<td>Repeat test every 6 months</td>
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<tr>
<td>Lipoprotein (a)</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Repeat test every 12 months</td>
<td></td>
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<tr>
<td><strong>CANCER</strong></td>
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<tr>
<td>Colon: Occult Blood Test</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repeat test every 12 months</td>
<td></td>
</tr>
<tr>
<td>Breast: Monthly self examination</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Repeat examination every month</td>
<td>Self examination will be taught by the physician.</td>
</tr>
<tr>
<td>Breast: Breast examination by a physician</td>
<td>X</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Repeat examination every month</td>
<td></td>
</tr>
<tr>
<td>Breast: Mammography</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Repeat test every year</td>
<td></td>
</tr>
<tr>
<td>Colon: Flexible Sigmoidoscopy / Barium Colon Graphy</td>
<td>X</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Repeat test every 5 years</td>
<td>One of the tests will be chosen by the physician.</td>
</tr>
<tr>
<td>Stomach: Helicobacter pylori</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td>Will be identified based on the initial results.</td>
</tr>
<tr>
<td><strong>OSTEOPOROSIS</strong></td>
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</tr>
<tr>
<td>Bone Densitometry</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Repeat test every year</td>
<td>Can be modified based on the initial results.</td>
</tr>
</tbody>
</table>
Nutrition Assessment and Recommendations

**Vitamin A**
- Recommended minimum intake for you: 4,000 IU
- Recommended maximum intake for you: 5,000 IU
- Current intake: 6,289 IU

**Vitamin B1 (Thiamine)**
- Recommended minimum intake for you: 1,2 mg
- Recommended maximum intake for you: 100 mg
- Current intake: 0,6 mg

**Vitamin B2 (Riboflavin)**
- Recommended minimum intake for you: 1,3 mg
- Recommended maximum intake for you: 200 mg
- Current intake: 1,5 mg

**Vitamin B3 (Niacin)**
- Recommended minimum intake for you: 16 mg
- Recommended maximum intake for you: 100 mg
- Current intake: 35 mg
# Menu Plan and Exchange Options

## Your Exchange Options During the Period of Reaching Optimum Body Composition

<table>
<thead>
<tr>
<th>Exchange Option</th>
<th>Choices per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk option</td>
<td>3</td>
</tr>
<tr>
<td>Meat option</td>
<td>6</td>
</tr>
<tr>
<td>Bread option</td>
<td>12</td>
</tr>
<tr>
<td>Vegetable option</td>
<td>5</td>
</tr>
<tr>
<td>Fruit option</td>
<td>5</td>
</tr>
<tr>
<td>Fat option</td>
<td>5</td>
</tr>
<tr>
<td>Alcohol</td>
<td>Maximum 20 grams per day</td>
</tr>
</tbody>
</table>

## Your Exchange Options During the Period of Maintaining Optimum Body Composition

<table>
<thead>
<tr>
<th>Exchange Option</th>
<th>Choices per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk option</td>
<td>3</td>
</tr>
<tr>
<td>Meat option</td>
<td>7</td>
</tr>
<tr>
<td>Bread option</td>
<td>15</td>
</tr>
<tr>
<td>Vegetable option</td>
<td>5</td>
</tr>
<tr>
<td>Fruit option</td>
<td>5</td>
</tr>
<tr>
<td>Fat option</td>
<td>6</td>
</tr>
<tr>
<td>Alcohol</td>
<td>Maximum 20 grams per day</td>
</tr>
</tbody>
</table>
Physical Activity and Exercise
Smoking Cessation

![Bar chart showing craving and stimulation levels](chart.png)
Diabetes risk in 10 years with optimum lifestyle and medical follow-up plan: % 12
Heart attack risk in 10 years with optimum lifestyle and medical follow-up plan: % 13
Lung Cancer Risk with Optimum Lifestyle and Medical Follow-up Plan
Breast Cancer Risk

Breast Cancer Risk with Optimum Lifestyle and Medical Follow-up Plan
Informing

Creating vulnerability perception

Follow-up programme & trainings

Awareness

Attitude change

Behavior change
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Chaos of terms and definitions in scientific and grey literature to describe personalized approaches to medicine and health care

- Personalized medicine
- Personalized health care
- P4 medicine (personalized, preventive, predictive and participatory)
- Precision medicine
- Stratified medicine
- Systems (bio)medicine
- ...

- Made mostly in a ‘top down’ manner by influential people and committees
- Focusing on ‘What is possible with available and upcoming technology?’
The other side of the coin: What do practices imply for the definition of personalized approaches?

• Identified 88 practices in the scientific literature with a systematic search strategy

• Not possible to categorize them based on technologies and methods they use.

• Approach: to analyze the content of practices without *a priori* analytical frameworks
The axes and their components that emerged from the analyzed practices

**Axis-1**
Application form and context
- Category-1: Practices available in health care market
- Category-2: Implementation models
- Category-3: Emerging practices

**Axis-2**
The group served - the ‘client’
- Group-1: Individuals
- Group-2: Health professionals
- Group-3: Health care organizations
- Group-4: Other organizations

Integration to health care
Main messages

- Implied definitions evolve as practices do
- Personalized medicine vs. personalized health care
  - Commodities and tools available in health care market -> Personalized medicine
  - Holistic approaches to individuals and their implementation in actual settings -> Personalized health care
- It is not only science and technology; health (policy and practice) and society domains must also be involved in realization of personalized health care.
- Integration to health care (based on three country examples: USA, France, Taiwan)
  - Attitude of the country to innovations
  - Health care system and policies
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A systematic approach to assess integration of Gentest into primary care services of a country

- Built on functions of health system, introduced within the Health Globe
- Gentest was used to exercise and identify which issues should be covered when investigating a country’s health system for integration of Gentest.
- This was enriched with examples provided from the Netherlands and the UK.
Assessment Areas

- Built on functions of a health system:
  - Stewardship
  - Financing
  - Health services (primary care services)
  - Resource generation
Stewardship

- Priority setting
- Legislation and regulations
- Steering
- Administration and management
Stewardship

- Priority setting
  - 1. Health policies, strategies and programmes
  - 2. Strategies on relevant applications and technologies
- Legislation and regulations
- Steering
- Administration and management
Stewardship

• Priority setting
  – 1. Health policies, strategies and programmes
  – 2. Strategies on relevant applications and technologies
• Legislation and regulations
  – 3. Regulation of non-diagnostic services which aim prevention
  – 4. Regulation of genetic testing, including predictive testing for implementation in primary care services
  – 5. Regulations on ethical issues in terms of implementation
  – 6. Regulations on liability of the practice model
  – 7. Regulations on data protection, privacy and confidentiality
  – 8. Regulations on cross-border health care
• Steering
• Administration and management
Stewardship

• Priority setting
  – 1. Health policies, strategies and programmes
  – 2. Strategies on relevant applications and technologies

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  – 8. Regulations on cross-border health care

• Steering
  – 9. General environment and culture of the health system for innovation
  – 10. Stakeholders, processes and mechanisms involved in implementation of new applications in health care

• Administration and management
Stewardship

• Priority setting
  – 1. Health policies, strategies and programmes
  – 2. Strategies on relevant applications and technologies

• Legislation and regulations
  – 3. Regulation of non-diagnostic services which aim prevention
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• Steering
  – 9. General environment and culture of the health system for innovation
  – 10. Stakeholders, processes and mechanisms involved in implementation of new applications in health care

• Administration and management
  – 11. Mechanisms related to evaluation of new applications and decision making in health care services
Financing

- 12. Health financing system of the country
- 13. General health expenditure structure of the country
- 14. Payment mechanisms for primary care services, i.e. GPs
Health Services
(Primary care services)

- 15. Strength and place of primary care services in the healthcare system and its relationship with other levels of care
- 16. Scope of primary care in terms of (primary) prevention
- 17. Performance assessment in primary care services
- 18. Service delivery in primary care services
Resource Generation

- Health workforce
- Knowledge
- Physical resources
Resource Generation

• Health workforce
  – 19. Health workforce in primary care services
  – 20. General environment and culture of the primary care services for implementation of a new practice model

• Knowledge

• Physical resources
Resource Generation

• Health workforce
  – 19. Health workforce in primary care services
  – 20. General environment and culture of the primary care services for implementation of a new practice model

• Knowledge
  – 21. Education and training of the health workforce
  – 22. Information flow and information systems

• Physical resources
Resource Generation

• Health workforce
  – 19. Health workforce in primary care services
  – 20. General environment and culture of the primary care services for implementation of a new practice model

• Knowledge
  – 21. Education and training of the health workforce
  – 22. Information flow and information systems

• Physical resources
  – 23. Logistical aspects
  – 24. Laboratory services
20. General environment and culture of the primary care services for implementation of a new practice model

- Job satisfaction and workload of GPs can play a role in their attitude towards health system.

- **Criteria and issues to be considered**
  - Job satisfaction levels of the primary care team members, in particular GPs and nurse practitioners
  - Current workload of GPs
  - Opinions and attitudes of GPs to new applications, in particular their attitudes towards health authorities and decision makers
  - Professional liability insurances and possible effects of the practice model on them

- **Examples from the countries**
  - GPs in the Netherlands might be reactive to any additional task in their job description since they already feel overloaded and overwhelmed.
  - GPs in UK who might be reactive towards the screening programmes that run in primary care.
  - If the country has professional liability insurance schemes, the practice of the model in primary care services may have an impact on the scope and premiums of the insurance scheme. Such effects may influence the willingness of the GPs to adopt the model in their practices.

- **Recommendations:**
  - The practice model should be implemented in a way that doesn’t increase the work load of the GP (and also the other primary care team members) and/or remunerate the additional labor required.
• Overall, this work provides a case example for a systematic approach to investigation of issues related to integration of a personalized preventive model into primary care services.
Outline

• Introduction
• Structure of the thesis
• Overview of the chapters and main results
  • Main conclusions
Main conclusions of the thesis

• Public health is what we do to reach “the attainment by all peoples of the highest possible level of health” (Objective of World Health Organization as described in its constitution) (Part I)
• Personalized health care offers opportunities to combat with the huge burden of chronic complex diseases.
• ‘Personalization’ is not only genes; one must address all determinants of health to personalize health care. (Part II)
• Gentest is an example to a comprehensive and innovative approach to prevention of complex diseases which focuses on earlier stages of disease development and progression (Part II).
• Personalized health care is not only about science and technology. For its realization, science, technology, health care (including policy and practice) and society domains should work collectively. (Part II)
• For integration of personalized health care practices into health services, it is crucial to look at the health care system in its entirety. (Part III)
Thank you!
Integration of a Personalized Health Care Model within Health Care Systems and Policies in Europe

Where to integrate?
- A framework for public health and health systems interrelations: Health Globe
- Looking at US Health System from European Perspective

What to integrate?
- A perspective on personalized health care
- Introducing the practice model: Gentest
- Debating the definition of personalized approaches: Content analysis of practices

How to integrate?
- A systematic approach to assess integration of Gentest into primary care services
<table>
<thead>
<tr>
<th>Inputs</th>
<th>Assessments</th>
<th>Optimum Lifestyle and Medical Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Personal information</td>
<td>• Nutritional assessment</td>
<td>• Medical evaluation</td>
</tr>
<tr>
<td>• Health information</td>
<td>• Body composition assessment</td>
<td>• Medical follow up plan</td>
</tr>
<tr>
<td>• Living and working conditions</td>
<td>• Assessment of physical activity and exercise</td>
<td>• Programme for optimum body</td>
</tr>
<tr>
<td>• Lifestyle information</td>
<td>• Assessment of causes of smoking</td>
<td>composition</td>
</tr>
<tr>
<td>• Nutrition</td>
<td>• Assessment of current health information</td>
<td>• Nutritional recommendations</td>
</tr>
<tr>
<td>• Nutritional habits</td>
<td>• Genotype assessment</td>
<td>- Menu plans</td>
</tr>
<tr>
<td>• Food consumption data using Gentest Food Portion Atlas</td>
<td>• Assessment of biomarkers</td>
<td>- Exchange options</td>
</tr>
<tr>
<td>• Physical activity and exercise</td>
<td>• Assessment of current risks of common complex diseases, i.e.</td>
<td>- Supplements</td>
</tr>
<tr>
<td>• Smoking</td>
<td>heart attack, stroke, type 2 diabetes, osteoporosis, cancers</td>
<td>• Physical activity and</td>
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<tr>
<td>• Anthropometric and bioimpedance measurements</td>
<td>(lung, breast, prostate, colon and stomach)</td>
<td>exercise recommendations</td>
</tr>
<tr>
<td>• Biomarkers</td>
<td></td>
<td>- Exercise programmes</td>
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<tr>
<td>• Genotype information</td>
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<td>• Recommendations on</td>
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<td></td>
<td></td>
<td>quitting smoking</td>
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| Follow up plan (optional)                                             |                                                                            |                                  |
| • Weekly, monthly, yearly evaluations                                 |                                                                            |                                  |
| • Revisions of the plans                                             |                                                                            |                                  |
• Idea development, 1998-1999 (WHO years of Dr. Serdar Savas)
• Planning, 2000-2004
• Preparations at Hacettepe University Science Park
• Establishment of GENAR Institute, 2004
  o GENAR Laboratory for Biotechnology and Molecular Genetics
  o GENAR Center for Nurigenetics and Lifestyle Research
  o GENAR Center of Personalized Medicine and Pharmacogenetics
• Development of the Gentest model and piloting 2004-2009
  o Gentest identified as a ‘Best Practice Model’ in Europe by Public Health Genomics European Network (2008)
• Marie Curie Fellowship of Tomris Cesuroglu (2011-2014)
• Implementation of Gentest in Istanbul, Ankara, Izmir, Bursa and Adana in Turkey, 2011 ->
TOGEN
Turkish Society of Public Health Genomics and Personalized Medicine

- Istanbul International Symposium on Nutrigenetics, 2005
- Establishment of ‘Nutrigenetics Society’ in Turkey, 2005
- Several conferences and trainings in Turkey
- Istanbul International Symposium on Public Health Genomics, 2009
Gentest is an endeavor to face the challenge of chronic complex diseases as an integrative preventive model which utilizes individual’s health information, lifestyle factors, biomarkers and genotype in order to prevent, early detect and treat chronic and complex diseases in a targeted way.