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# **BIRO Target Indicators**

**WP2 – Clinical Review  
Target Material**

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# Agenda

- Work package targets
- Literature Search: Preliminary results
- Target material
- Clinical Review process
- Indicator Classification



# **WP2 Targets**

## **Introduction**

- Provide evidence for
  - the selection of indicators and
  - meta information
- Outputs of WP2 will provide input to
  - WP3 – common data set
  - WP4 – data dictionary
  - WP7 – reports template (not mentioned in work plan)
- Definition of clear-cut benchmarks
  - measurable entities for translation to mathematical algorithms



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# **WP2 Targets**

## **Extraction and appraisal**

- Mainly use secondary literature
  - guidelines, meta-analyses
  - Systematic extraction of scientific papers only if required for specific questions
- Appraisal of indicators relating to „selection criteria“
  - relevance: different domains
  - scientific soundness
  - feasibility



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## **WP2 Targets**

### **Adjustment to state-of-the-art**

- Well established concepts in different regions might not be changeable
  - come up with recommendations on how to handle such differences
  - requirements for technical modules
  
- Example: HbA1c



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# Example

- Example:
  - guidelines say: "it is important to lower blood pressure under 140/90 in diabetic patients; best treatment option is lifestyle modification; if that fails use antihypertensive agents"
  - There is insufficient documentation of lifestyle intervention (need to recommend strategy)
  - Value 140/90 is subject to discussion (blood pressure is needed as a numerical values to define flexible cutoffs).
  - possible core process can be of the form: "patients with blood pressure < 140/90 with/without medication", "blood pressure > 140/90 with/without medication"



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# Clarification of Terms





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# Clarification of Terms

- Data Item = Parameter
  - a „class“ of information to be collected
- Indicator
  - aggregated data for health reporting
- Report template
  - indicators + representation (tables, graphs)
  - additional text (description, comments)





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# Literature Search

Preliminary results





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# Literature Search Epidemiology

- Epidemiology of diabetes
  - Yearly incidence of Type 1 Diabetes (per 100.000 people)
  - Yearly incidence of Type 1 Diabetes in children between 0-14 years of age at diagnosis (clinical) (per 100.000 children)
  - Yearly incidence of Type 2 Diabetes (per 100.000 people)
  - Diabetes (Type 1 and 2) prevalence (per 1000 people)
  - Prevalence of impaired glucose tolerance
  - How was diabetes diagnosed?
  - Annual death rate /100,000 general population, adjusted for European Standard Population
    - in patients who have as primary or any cause of death diabetes mellitus
    - in the general population from all causes



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## Literature Search Risk profile

- Obesity
  - BMI
- Physical inactivity
  - No instrument known
- Nutritional habits
  - No instrument known
- Gestational diabetes
  - see Diagnosis

? Does BIRO include only patients with diagnosed diabetes, or do we start with diabetes risk?

# Literature Search

## Diagnosis and classification

- Diagnosis
  - Date/Year of diabetes diagnose
  - Fasting plasma glucose (FPG)  $\geq 7,0$  mmol/l
  - 2 h OGTT (75g) – Plasma glucose optional  $\geq 11,1$  mmol/l
- Classification
  - WHO classification
    - main categories: Type 1, Type 2, gestational, other
    - more fine grained sub-categories available
  - NHS
    - pre-diabetes stages:  
Impaired glucose tolerance/fasting glucose
    - MODY (maturity onset diabetes of youth)
  - DiabCare
    - Gestational diabetes not defined



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# Literature Search

## Risk profile for complications and intermediate outcomes

- Glucose level
  - HbA1c
    - if insulin treated in combination with hypoglycaemic episodes
  - single BG measurements not recommended
- Blood Pressure
  - systolic, diastolic
  - method of measurement
  - year of diagnosis of hypertension
- Lipids
  - fasting triglycerides, LDL (effect in clinical studies)
  - HDL (meaningful in epidemiology)
  - Total cholesterol, Total cholesterol/HDL  
(Friedemann equation for LDL calculation)



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# Literature Search

## Risk profile for complications and intermediate outcomes - 2

- Weight
  - see obesity
- Smoking
  - Smoking status
  - Cigarettes per day
  - Support in smoking cessation
  - Pack-years (?)
- Alcohol
  - average intake (per week)
    - NHS uses units (= 10g), DiabCare uses gramms
- Physical activity
  - not easy to categorize, NHS has a definition



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# Literature Search

## Risk profile for complications and intermediate outcomes - 3

- Foot Screening
  - Former ulcer/amputation (above/below ankle)
  - Skin and nail status, muscle atrophy, deformations, hyperkeratosis, temperature
  - Control of footwear
  - Foot examination: neurological examination with examination of reflex status, vibration, pain and pressure sensation (bilateral)
  - Palpation of foot pulse
  - Peripheral revascularization
  - Existing documentation
    - NHS uses classification which is a combination of the above parameters
    - DiabCare uses some of these items, but no Wagner/SanAntonio
    - DMP Germany uses Wagner SanAntonio



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# Literature Search

## Risk profile for complications and intermediate outcomes - 4

- Eye Screening
  - Exam within the past 12 months
  - Photocoagulation
  - Vitrectomy
  - Cataract affecting eyesight





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# Literature Search Management and care of Diabetes and its co-morbidities

- Glucose control: Oral therapy
  - OAD treatment (y/n)
    - Biguanides, Sulfonylurea, Glucosidase inhibitors, Glitazones, Glinides
      - treatment with substance,
      - contraindication,
      - dosage per day
- Glucose control: Insulin therapy
  - Insulin treatment (y/n)
    - Human insulin / Insulin analogues
    - Units per day
    - Pump therapy
    - Long/short acting insulin
    - Type of insulin therapy (CIT, MDI, ODI, PIT)
      - item for dosage adjustment in patient self management



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# Literature Search Management and care of Diabetes and its co-morbidities - 2

- Diet
  - diet (only)
- Blood pressure control
  - Blood pressure treatment (y/n)
    - Diuretics,  $\beta$ -Blockers, Ca-Antagonists, ACE inhibitors, Angiotensin Receptor Blockers (AT II Blocker), Alpha-Blockers, Others
    - contraindication
    - dosage per day
- Lipid lowering therapy
  - yes/no
    - Statins: Simvastatin, Pravastatin, Atorvastatin,...
    - Fibrates



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# Literature Search Management and care of Diabetes and its co-morbidities - 3

- Treatment of cardio vascular disease !!relevance??
  - coronary revascularization
  - Thrombolytic therapy

## Literature Search

# Self and lifestyle management

- Self monitoring and life style interventions
  - Blood glucose (Y/N, controls/week)
  - Blood pressure home measurement (Y/N, controls/week)
  - Glucosuria self measurement (Y/N, controls/week)
  - Personal insulin dose adjustment
  - Life style interventions: see diet, exercise and education
- Education/Empowerment
  - Specific education for glucose lowering therapy
  - Podiatric education
  - Hypertension education
  - Inpatient/outpatient education
  - Structured/evaluated patient education program
  - Extent of patient education program (duration, units...)
  - Self-help groups (membership, contact with)
  - Target agreements (HbA1c, blood pressure, diet, smoking, ...)



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## Literature Search

# Self and lifestyle management

- Psychological care, screening for depression
  - WHO wellbeing 5
  - EUROQOL



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# Literature Search Complications

- Acute Complications
  - Hypoglycaemia
  - Hyperglycaemia/Ketoacidosis
- Eye complications
  - Blindness
  - Retinopathy: (non) proliferative, mild, severe
  - photocoagulation (complication or therapy?)
  - Maculopathy (diabetes related?)
  - Severe vision loss (?)



## Literature Search

# Complications - 2

- **Kidney damage/Nephropathy**
  - ESRD (end stage renal disease = ESRF end stage renal failure)
    - Percent with serum creatinine tested in last 12 months
    - Percent with ESRD in last 12 months
    - Annual incidence of dialysis and or transplantation (renal replacement therapy in patients with diabetes/1,000,000 general population
    - Prevalence (stock) of dialysis/transplantation (renal replacement therapy) in patients with diabetes/1,000,000 general population  
(type of renal replacement therapy, nephropathy incipient/manifest)
- **Foot complications**
  - Acute ulcer/amputation
  - Infection: Wagner classification/ San Antonio Wound classification
  - Foot deformities, Charcot
  - Regulary visits at diabetic foot clinic
  - Pharmacologic therapy on foot disease



## Literature Search

# Complications - 3

- Neuropathy
  - neuropathy
  - erectile dysfunction / sexual dysfunction (?)
- Cardiovascular complications (CVD)
  - Myocardial Infarction (MI)
  - former MI
  - Angina pectoris
  - CHD (coronary heart disease) - risk
  - Stroke (=apoplexy)
- Peripheral vascular disease
  - PVD (peripheral vascular disease) (= german PAVK)





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## Literature Search

# Demographic and socio-economic factors

- Individual characteristics
  - Age
  - Gender
  - Age at onset
  - Ethnicity
- Population
  - Total population
  - Median age of population, percentage -15 – 15 – 65 – 65+
  - Rate of urbanisation
  - Life expectancy & related indicators
  - Sick days per year and person
  - Hospital days per year and person (diabetes related?)
- Socio-economic factors
  - Literacy rate
  - Total labour force
  - Total employment
  - Total unemployment



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## Literature Search

# Health system & health care delivery

- Health care resources
  - Facilities: hospital beds total (acute care / rehabilitation)
  - Manpower: physicians (GPs, specialists), nurses, pharmacies, ophthalmologists...
  - Education of personnel
- Health care delivery
  - Inpatient care utilisation (days per hospitalisation, hospitalisation rate per 1000 inhabitants)
  - Outpatient care utilization (GP contacts per patient and year)
  - Medicine use/medical aids
  - Gatekeepers



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## Literature Search

# Health system & care delivery - 2

- National expenditure on health (% of GDP)
- Public and private expenditure on health
- Expenditure on medical services (inpatient stays, outpatient care, medical aids, pharmaceuticals)
- Medical goods dispensed to outpatients
- Total health expenditure by age group
- Health expenditure by fund source



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# Literature Search Metadata, Documentation

- Recording
  - electronic, paper, online
- Reliability
  - Bias
  - Completeness
- Source
  - Documentation, Registries, DiabCare System, Surveys, Accounting systems, Sentinel Practice Surveillance Network (SPSN), Insurance/Reimbursement, Patient associations



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## Selection of Target material





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# Target Material

- Health Indicators
  - EUDIP ✓
  - ECHI ✓
  - OECD ✓
- Guidelines
  - IDF ✓
  - SIGN ✓
  - Consensus on diabetic foot ✓
  - New Zealand
  - ADA
  - Canada
  - German Diabetes Association



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# Clinical Review Process





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# Clinical Review Process

- Identify a large evidence base (WPL)
  - review of selected documents
  - various material supplied by partners
  - additional targeted search
- PCB receives and discusses reduction to “core evidence base”
- WPL receives data set definitions from WP3/4
- WPL extracts indicators, benchmarks, parameters and basic concepts from the literature → long list
- panel members indicated by partners reduce the list by voting on indicators on the basis of selection criteria → core evidence based information set





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# Next Steps

- Select target material
- Determine Selection criteria for parameters
  - relevance (different domains)
  - feasibility
  - scientific soundness
- Deliverable 1 – May 31st, 2006
- Review by partners
  - comments
  - consensus
- Long list
- Short list



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# Output

## Clinical review report

- Step 1: data items
  - e.g. HbA1c
  - Source
    - clinical guidelines
    - clinical studies
    - other initiatives (feasibility)
  
  - **Data items**
    - have a clinical/administrative definition
    - are direct input for WP3/4
- Step 2: indicators
  - e.g. average HbA1c in type 2 diabetes patients older than 65
  - Source
    - previous indicator projects
    - existing indicator definitions
    - state-of-the-art health reports
    - epidemiological material ??
  - Composition of indicators from data items
  
  - **Indicators**
    - are final output of WP1
    - interact with WP3/4 + WP7



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# Indicator Classification

- Outcome Indicators
  - Risk profile, intermediate outcome
  - Epidemiology of diabetes incidence, prevalence, ...
- Clinical Guidelines
  - Interventions and their impact treatments, examinations, empowerment
- Meta-data
  - data characteristics
- Health system related
- Patient level
  - intermediate outcome (risk profile)
  - Long term outcomes incidence, prevalence, ...
  - Determinants ●
- Provider level
  - Processes (indirect outcomes) treatment, glucose levels ● examinations, empowerment
  - Systems of care organisation
- 
- Health system level