

Verification of Medical Guidelines

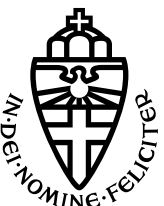
using Task Execution with Background Knowledge

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Protocure

Background

The trend of the last decade has been to base clinical decision making more and more on sound scientific evidence, i.e., *evidence-based medicine*. This has led medical specialists to develop medical guidelines for promoting standards of medical care. Guidelines are structured documents providing detailed steps to be taken by health-care professionals in managing the disease in a patient. It has been shown that guidelines can improve health-care outcomes and may reduce the costs of care up to 25%.

Problem Statement

Medical guidelines should not be considered static objects as new scientific knowledge becomes known on a continuous basis. Rapidly changing evidence makes it difficult to keep guidelines up to date. Checking the quality of a guideline may help in the maintenance of guidelines.

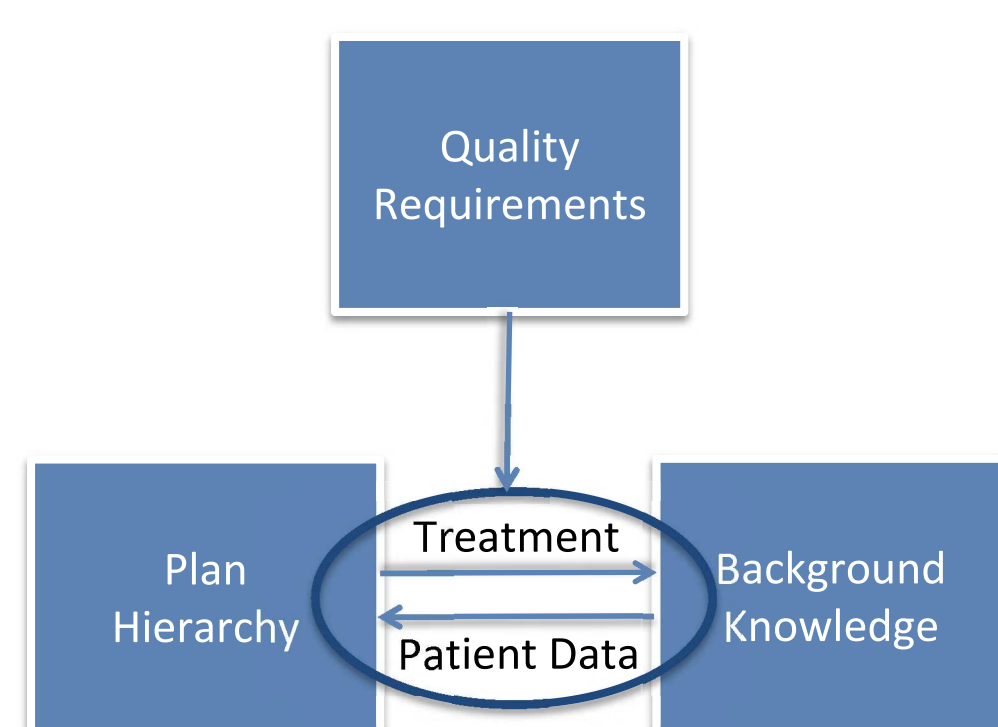
Aims

We use formal methods for quality checking of medical guidelines. We are mainly concerned with the meta-level approach which we use to formalise general quality criteria of good practice medicine a guideline should comply to. Our formalisation of quality criteria and medical background knowledge is used to interactively verify the quality of a guideline dealing with the management of diabetes mellitus type 2 (DM2).

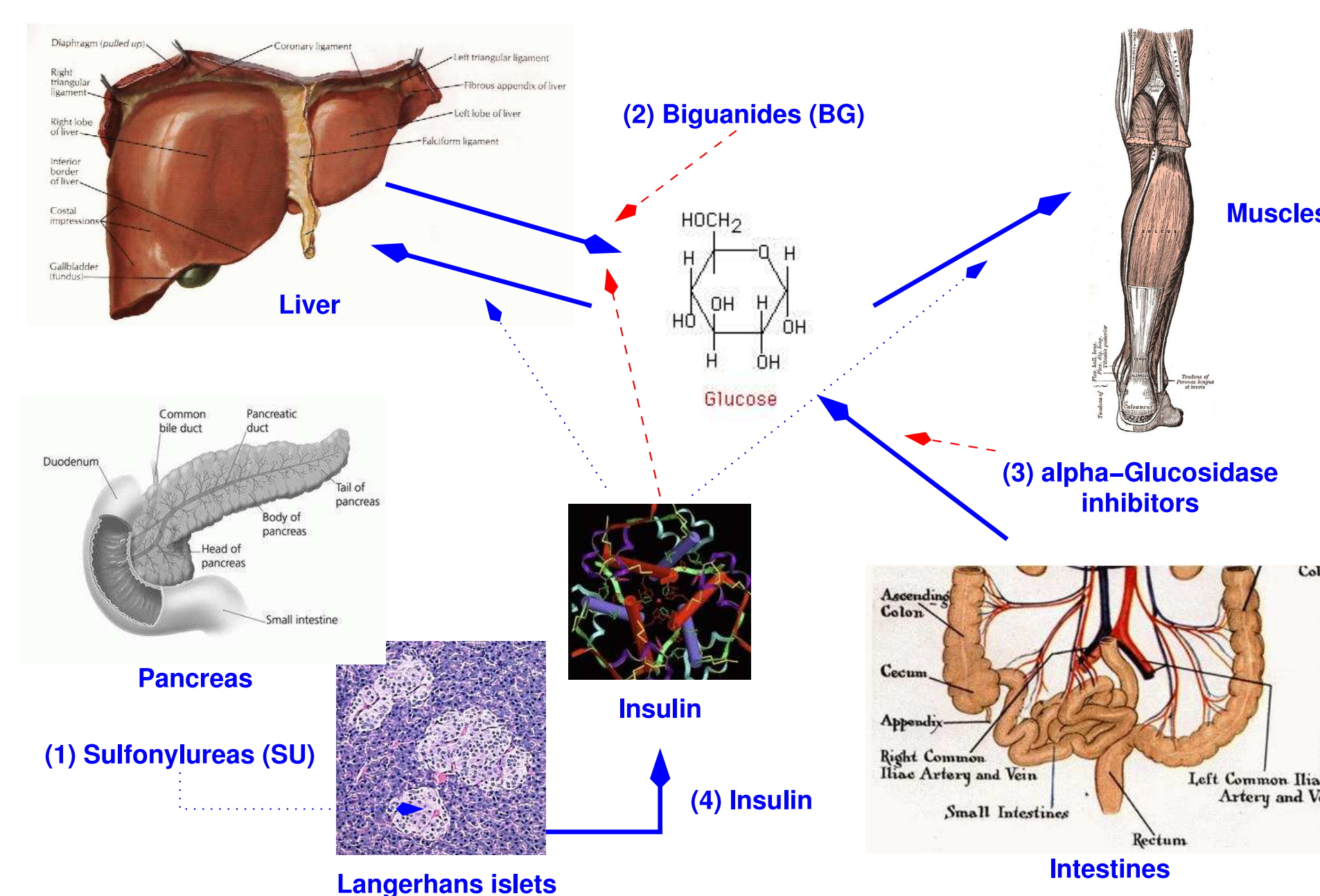
Verification Framework

For verifying the quality of medical guidelines, we assume that there are at least three types of knowledge involved in detecting the violation of good practice medicine:

1. Knowledge concerning the (patho)physiological mechanisms underlying the disease, and the way treatment influences these mechanisms (*background knowledge*).
2. Knowledge concerning the recommended treatment at each stage of the plan and how the execution of this plan is affected by the state of the patient (*order information from the guideline*).
3. Knowledge concerning good practice in treatment selection (*quality requirements*).



1. Causal Modelling of Medical Background Knowledge



The (patho)physiological mechanisms have been formalised with a first-order predicate knowledge:

$knowledge : patient \times patient$

For example,

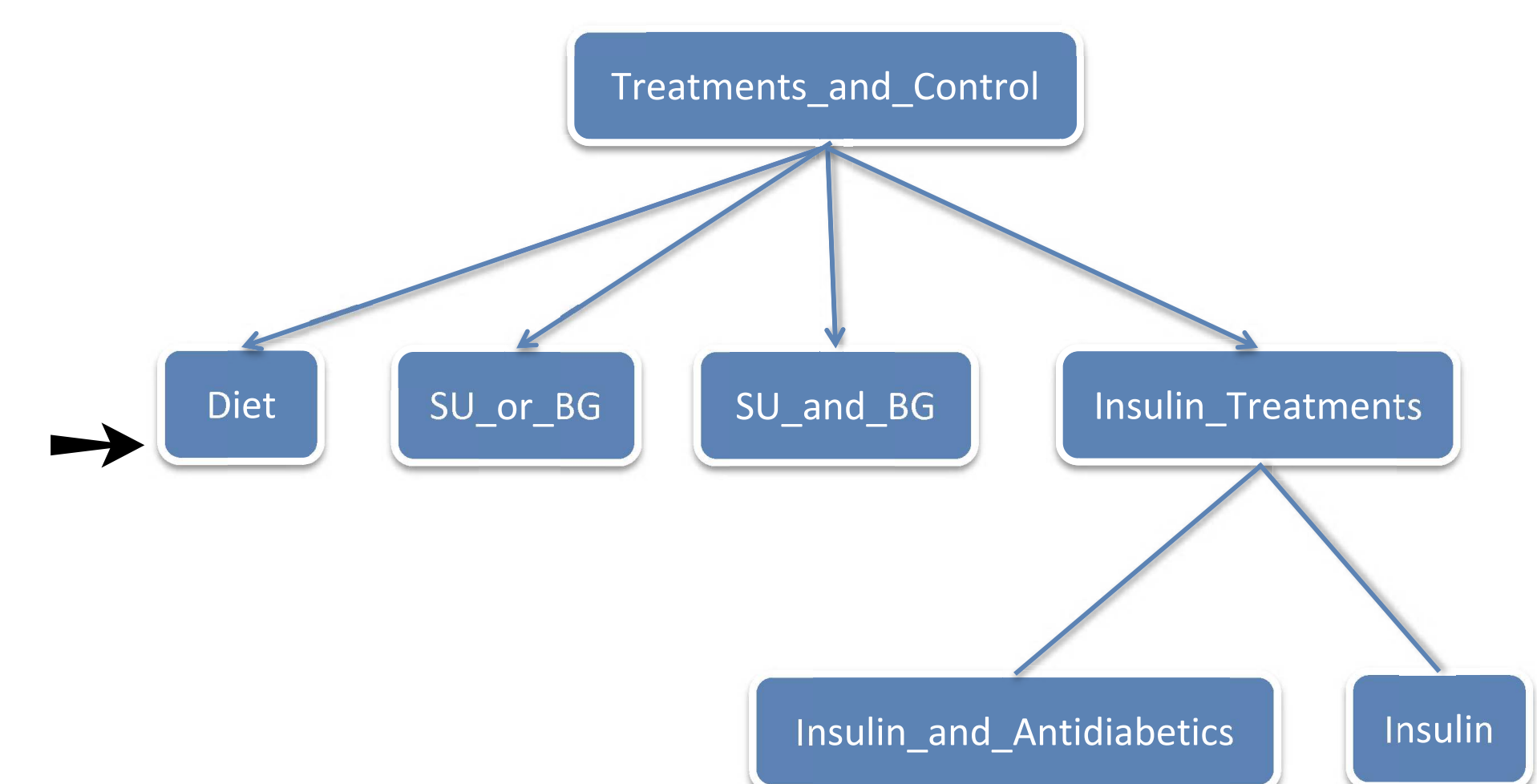
$knowledge(pre, post) \rightarrow$
 $(post[‘uptake(liver,glucose)’] = up \wedge$
 $post[‘uptake(peripheral-tissue,glucose)’] = up) \wedge$
 $pre[‘capacity(B-cells,insulin)’] = exhausted \wedge$
 $pre[‘condition’] = hyperglycaemia$
 $\rightarrow post[‘condition’] = normoglycaemia)$

This axiom phrases under what conditions you may expect the patient to get cured, i.e., when the patient suffers from hyperglycaemia and insulin production of his B cells are exhausted, an increased uptake of glucose by the liver and peripheral tissues results in the patient condition changing to normoglycaemia.

2. Temporal Treatment Order in DM2

The following fragment is part of the guideline for general Dutch practitioners about the treatment of diabetes mellitus type 2:

- Step 1: diet.
- Step 2: if quetelet index (QI) ≤ 27 , prescribe a sulfonylurea (SU) drug; otherwise, prescribe a biguanide (BG) drug.
- Step 3: combine a sulfonylurea (SU) and biguanide (BG) drug (replace one of these by a α -glucosidase inhibitor if side-effects occur).
- Step 4: one of the following:
 - oral antidiabetic and insulin
 - only insulin



3. Meta-Level Quality Requirements

Firstly, we define the notion of a *proper* guideline. Let B be medical background knowledge, P be a patient group, N be the medical intentions one wants to achieve, and M be a medical guideline. Then M is called a *proper guideline* for a patient group P , denoted as $M \in Pr_P$, if:

Consistency: The guideline does not have contradictory effects.
 $B \cup M \cup P \not\models \perp$

Covering: The guideline eventually handles all the patient problems intended to be managed.
 $B \cup M \cup P \models \diamond N$

Secondly, if, in addition to these two axioms, for a preference relation \preceq_φ it holds that

Optimality: $O_\varphi(M)$ holds, where O_φ is a meta-predicate standing for an optimality criterion or combination of optimality criteria φ defined as: $O_\varphi(M) \equiv \forall M' \in Pr_P : \neg(M \preceq_\varphi M')$,

then the guideline is said to be *in accordance with good practice medicine* w.r.t. criterion φ and patient group P , which is denoted as $Good_\varphi(M, P)$.

Interactive Verification

Using the interactive verification tool KIV, we have verified the quality requirements mentioned.

For example, we verified that the order of any two treatments in the guideline was consistent with the preference order \leq , which minimises drugs and number of insulin injections:

$\square \forall_T (Tick \wedge T = Patient[‘treatment’] \rightarrow \square (\text{last} \vee (Tick \rightarrow \neg(T \leq Patient[‘treatment’]))))$

Verification of such quality requirements could be done with a high degree of automation of up to 90%.



Conclusions

We have setup a **framework** for the verification of medical guidelines and have developed a **meta-level theory of quality requirements** for good practice medicine. Using this framework and theory together with a model of background knowledge of glucose level control in diabetes management, we have **verified the quality of a medical guideline used in practice** by the Dutch practitioners. Thereby, it has been shown that the **approach is feasible**, with a **high degree of automation**.

References

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