

De Beste Spiegel: Dried Blood Spots als nieuwe manier om immuunsuppressiva te monitoren

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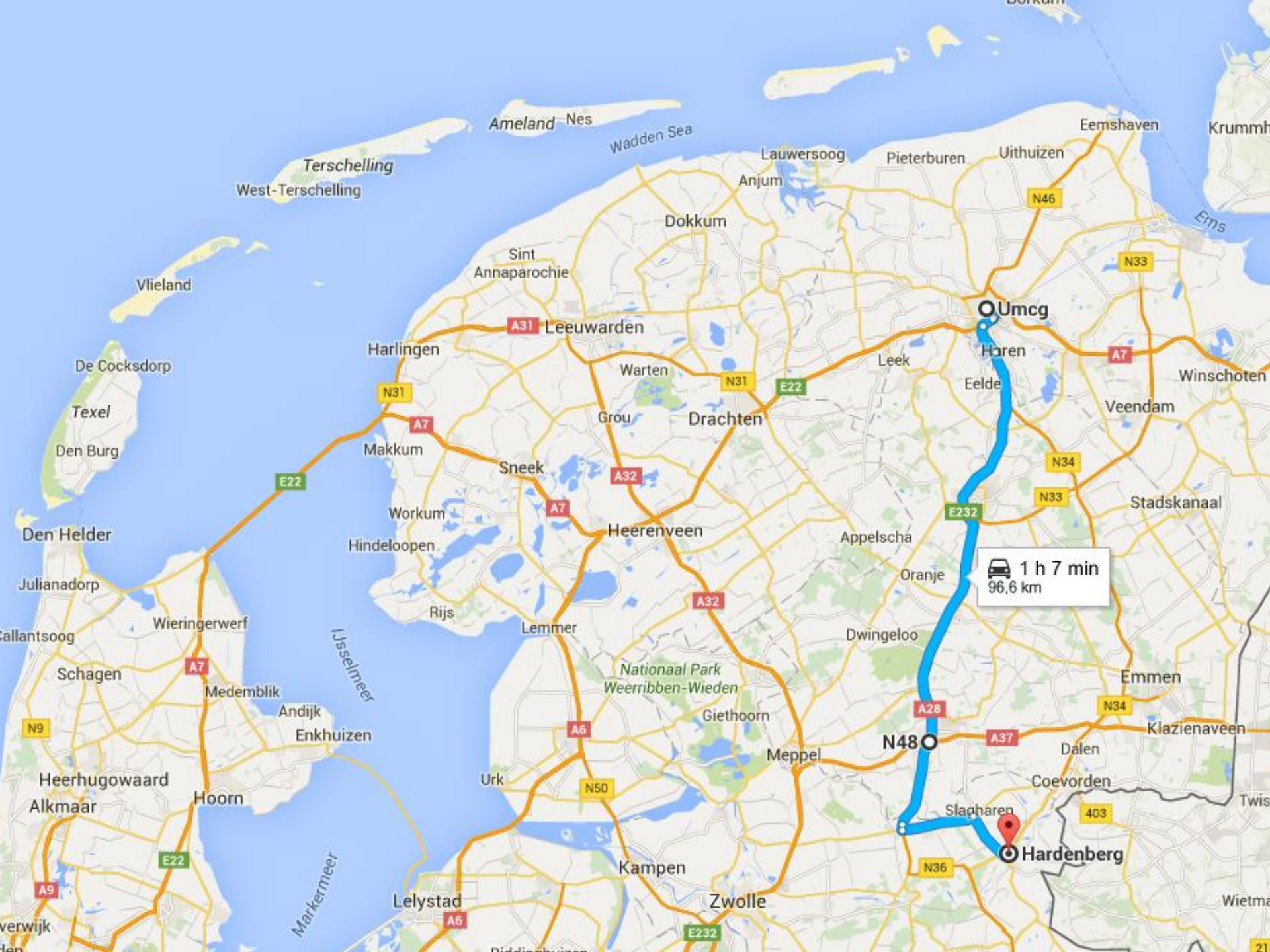
University Medical Center Groningen



ZonMw

Overview

- Analysis of drugs in dried blood spots: steps to take
 - Method
 - Clinical validation
 - Patient instructions (card, video)
 - Logistics
 - Go-life
 - Pharmaco-economic evaluation
- Conclusions



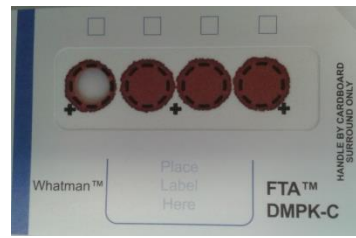
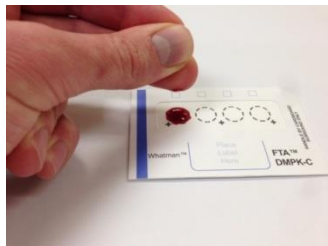
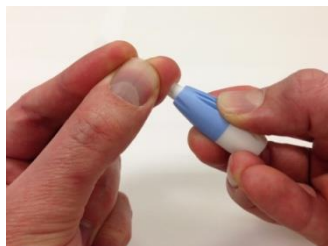
 1 h 7 min
96,6 km

Bloedspot = Home sampling!

- If the results are OK, an outpatient clinic visit can be avoided.



Dried Blood Spot analysis *step by step*



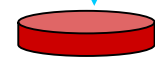
RESULT



Toegang tot uw
medische gegevens?
Vraag hier
mijnUMCG aan.

Dat kan direct met een
geldig legitimatiebewijs
en mobiele telefoon.

Wij helpen u graag!





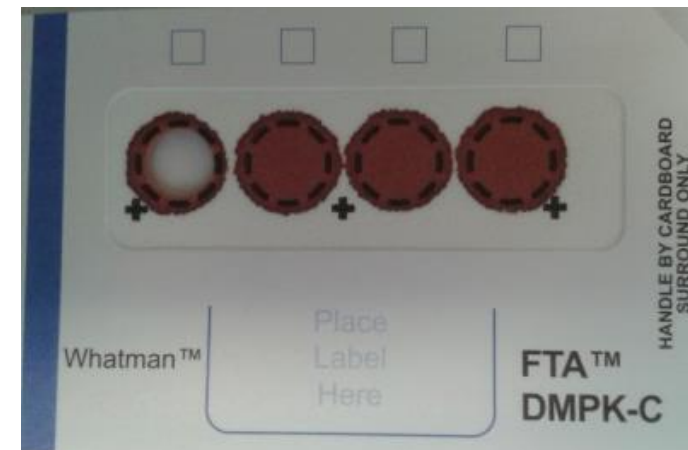
Hurdles to take

- Assay needs to be developed and analytically validated
- All necessary measurands need to be available in the assay
 - Step 1: clinical validation: demonstrate equivalence of method
 - Step 2: organise availability and distribution of DBS kits
 - Step 3: organise ICT so instruction letter for patient is printed and results are available for physician and for patients
 - Step 4: organise logistics with all partners involved, internally and externally
 - Step 5: develop easy-to-understand patient instructions
 - Step 6: give patient instructions how to assure quality of DBS before sending in



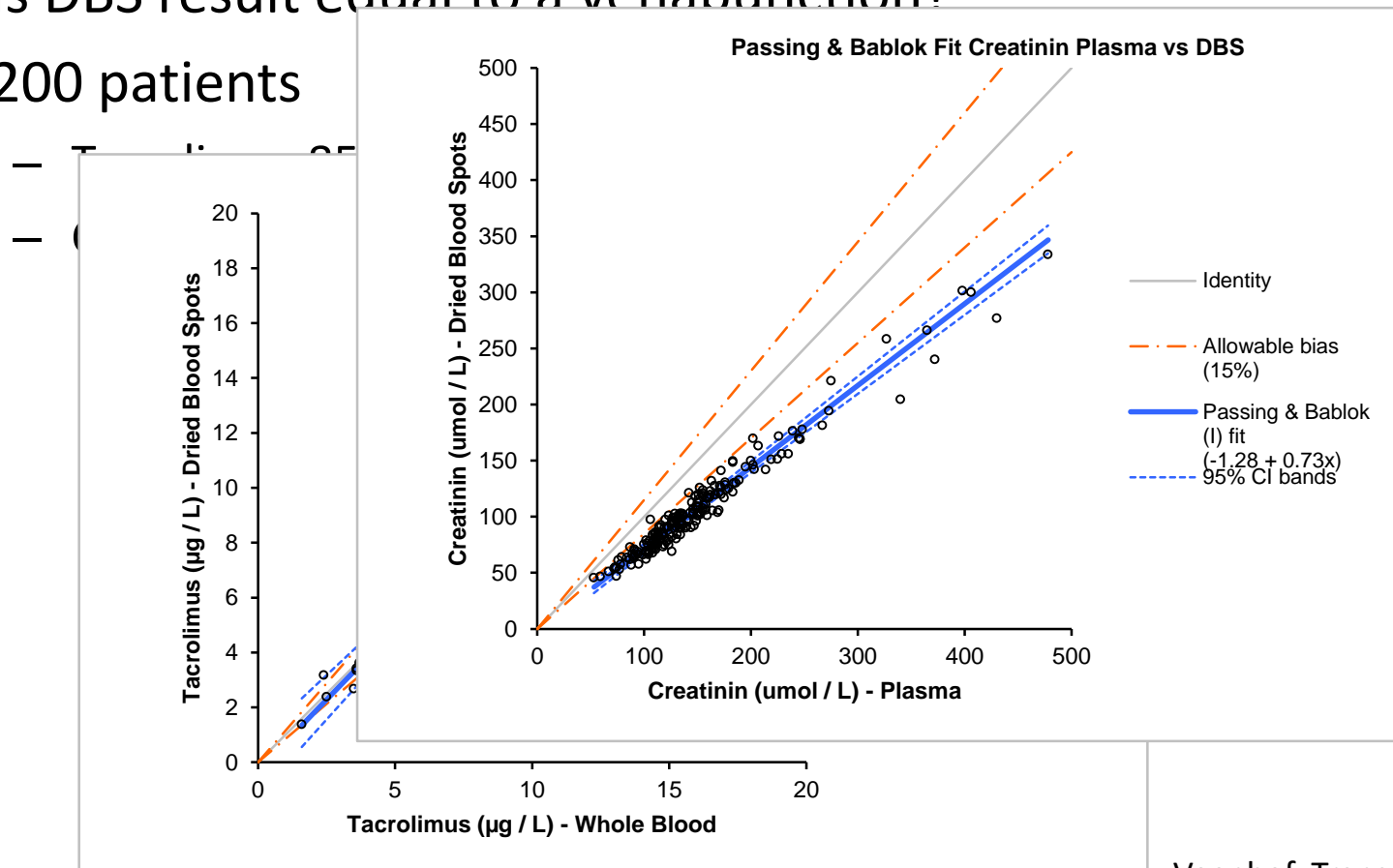
DBS

- Development of the assay:
 - Not part of the implementation, development is a difficult track that took several years



Clinical validation tacrolimus and creatinine

- Is DBS result equal to a venapuncture?
- 200 patients





Patient training by instruction video

The screenshot shows a web browser window with the following elements:

- Browser Address Bar:** Shows the URL "Universitair Medisch Centrum Gron... (NL)" and a search bar with the text "Zoeken".
- Page Header:** Features the UMCG logo and the text "Clinical Pharmacy and Pharmacology".
- Navigation Menu:** Includes links for "Patiënten", "Professionals", "Producten en diensten", "Research", "Onderwijs en opleidingen", and "Over de afdeling".
- Breadcrumbs:** Shows the path "Clinical Pharmacy and Pharmacology > Dried blood spot > Instruction video".
- Content Area:**
 - Title:** "Instruction-video Dried Blood Spot (DBS)" with a "Print" icon.
 - Left Sidebar:** A menu with options: "Procedure", "Instruction video" (highlighted with a plus sign), and "Forms and leaflets".
 - Video Player:** A large video player with the text "Instruction-video Dried Blood Spot" and "Drug concentration monitoring by using the finger prick method". A play button is visible in the bottom right corner of the video frame.
- Right Sidebar:** Contains a "Print" icon and a "DBS in t" link.
- Footer:** Includes social media sharing icons for Facebook, LinkedIn, Twitter, and Email, with the text "Share this:".

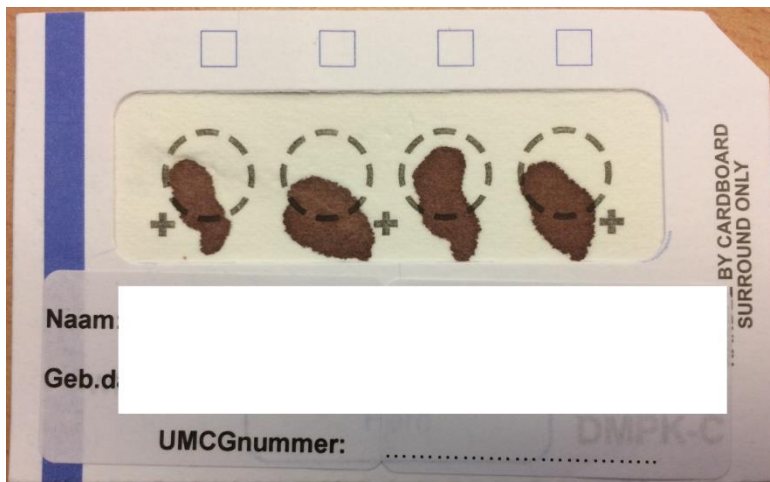
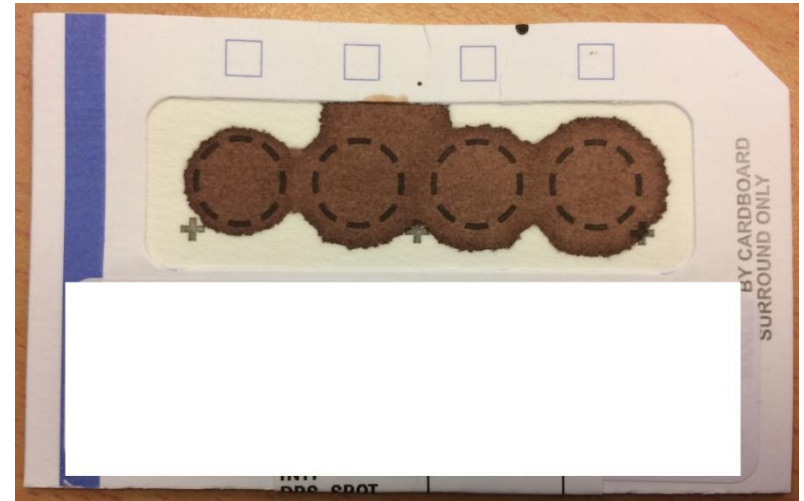
Sample logistics / ICT

- Availability of bloodspot kits for the patients
- Distribution of the bloodspot kits to the patients
- External logistics: KPN, special enveloppes
- Internal logistics of the samples
- Ordering and reporting results

October 2016



Real life results





Quality Control of the sample

Requirement:

- The patient should be able to decide at home if the sample is of sufficient quality to mail the card



Dried Blood Spot App

- The app is a responsive web-based application accessible in a browser on smartphone/pc/tablet
 - Check RGB code pixels
 - Check roundness
 - Check size for punch
- Performance
- User friendliness

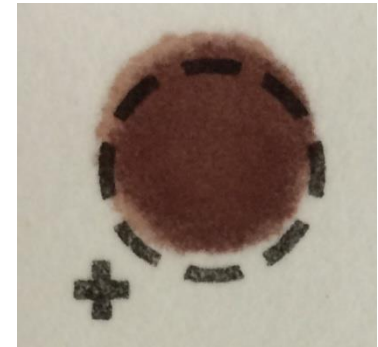




Performance results



- Performance test on 221 samples
- Performance 90,0%
 - 4,1% false positive
 - 5,9% false negative
- 95,9% sending in good quality sample
- Patients rated the app as user friendly
- Sufficient for clinical application



Cost-effectiveness

- Randomised trial
- 25 patients classical way trip to hospital for venapuncture
- 25 patients DBS
- Aim:
 - 20% reduction in outpatient clinic visits
 - Increase of patient satisfaction

Cost-effectiveness

- Interim results
 - No difference in outpatient clinic visits
 - Increased patient satisfaction
- Remarks/discussion cost-effectiveness:
 - KPN and internal logistics for DBS hard to organise, DBS results were often too late
 - DBS not suitable early after transplant, possibly in later phase when outpatient clinic visits are less frequent

Conclusions DBS

- Development of assay for DBS sampling by transplant patients is feasible, however not for every compound
- Home sampling possible using DBS, proper quality control is needed
- Quality control of sampling is possible by App
- Results are not suitable for making clinical decisions in the early phase after transplantation
- Operational in UMCG for patient monitoring of immunosuppressants, TB drugs, antifungal drugs, clozapine
- Logistics is a headache dossier if time to result is critical such as the early phase after transplant

- Many thanks to:
 - Stephan Bakker, MD, PhD
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 - Remco Koster, PhD
 - Herman Veenhof, MSc
 - Patient panel
 - Students
 - Staff outpatient department



Stellingen

- DBS is alleen zinvol indien alle noodzakelijke parameters erin gemeten kunnen worden
- DBS is alleen zinvol als de patiënt thuis kan controleren of de kwaliteit van het monster goed is
- DBS is alleen zinvol bij optimale externe en interne logistiek
- DBS is alleen zinvol bij polikliniekbezoek interval >1 week