CONSENT FOR SECONDARY USE OF DATA AND MATERIALS: THE GATE WIDE OPEN?

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Marjanka Schmidt

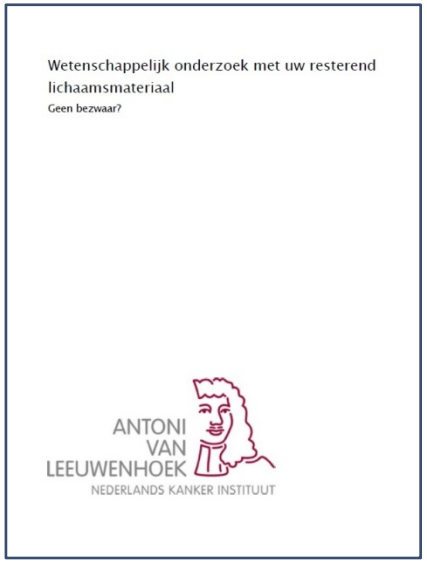
PATIENT CONSENT FOR SECONDARY USE OF TISSUE FOR SCIENTIFIC RESEARCH

- 97-99% (2007-2009)
- 95% (2% no, 3% don’t know) (2012-2014)

Vermeulen et al EJC 2009, BJC 2009; Rebers et al PLoS ONE 2016

PREVIOUS FINDINGS CONSENT PROCEDURES

- Opt-in vs. opt-out procedures
- 84% patients prefer a procedure with information
- High barriers to consenting lead to low consent rates and bias
- AVL: continuation opt-out with new brochure



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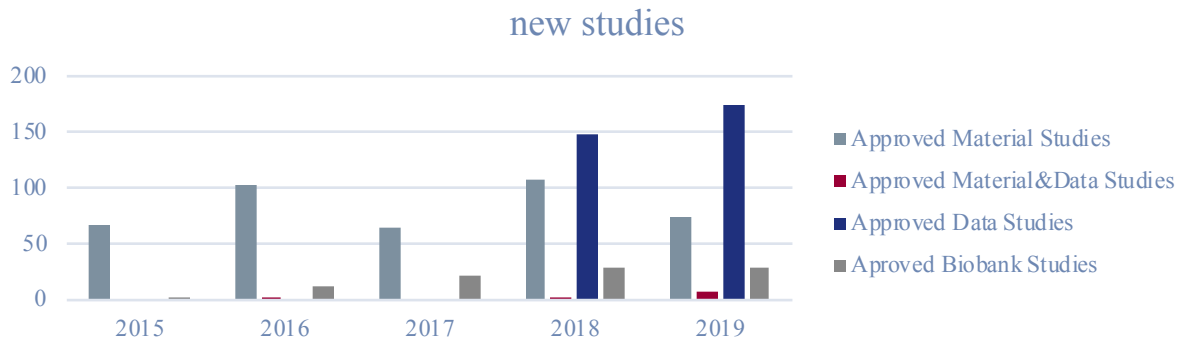
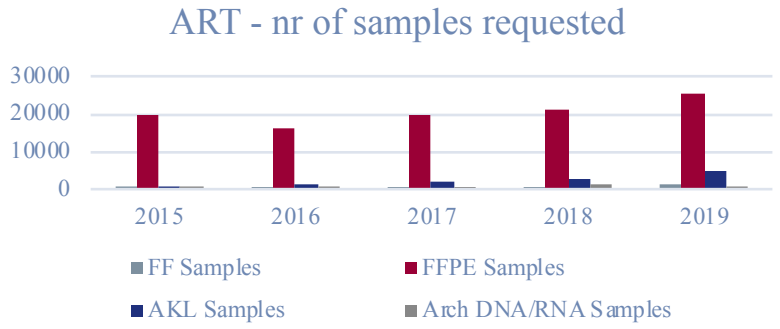
TIMES ARE CHANGING

- Societal norms
- Legal landscape
- More transparency needed for e.g.:
  - PDX models, organoids etc.
  - Whole genome sequencing
  - International sharing of data/materials

INCREASING NUMBER OF STUDIES AND SAMPLES





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NEW CONSENT PROCEDURE: CONSENT ‘AT THE GATE’

NEW CONSENT PROCEDURE: “BROAD” CONSENT

- Consent includes: e.g. PDX models, WGS, international sharing of data

- Consent excludes: trials, additional biopsies, questionnaires

CONSENT NOTED ELECTRONICALLY

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THE PROCESS

- Start October 3rd 2018

- October-November 2018:
  - Evaluation
  - Conversations with employees and team leaders to improve procedure
  - Patient interviews

- May 20th 2019: 31,500 patients received letter + brochure with option to opt-out.

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THE PROCESS

- May 29th 2019: Animation on narrow casting screens
- October 18th 2019: Pop-up in Hix
- Somewhere in 2020 (?): Notification on patient registration pillar

PROGRESS AND ANSWERS: ‘NO ANSWER’ ISSUE

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No answer at intake

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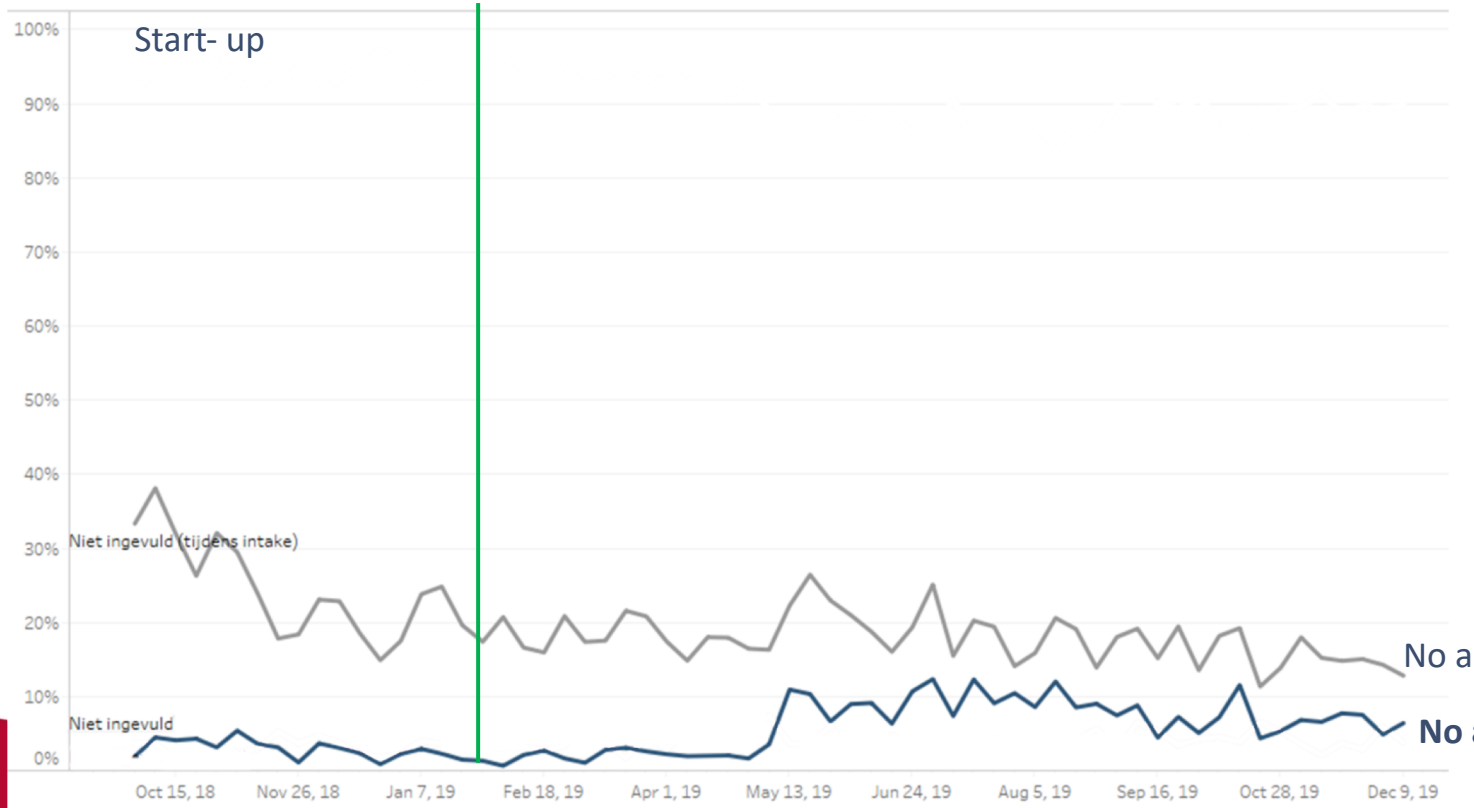

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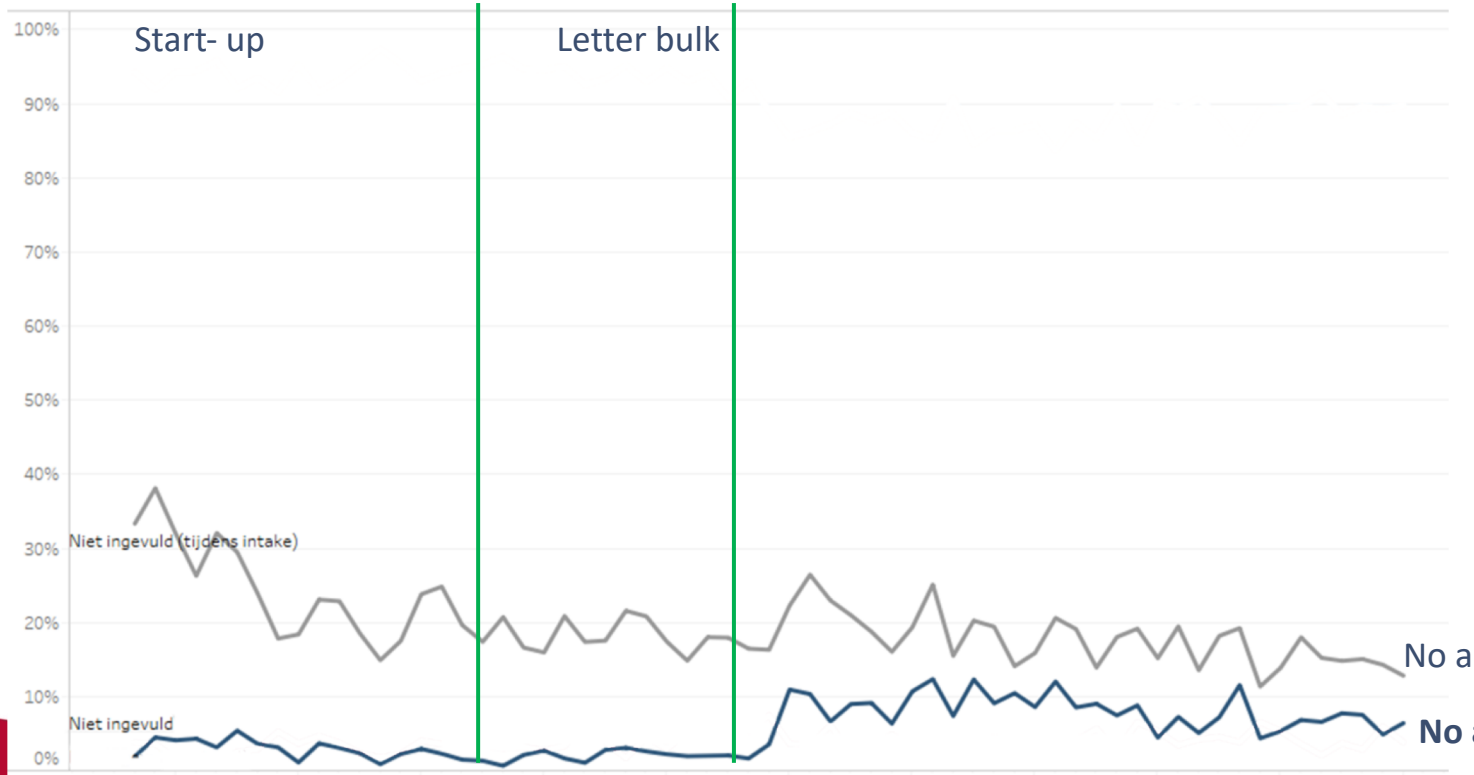

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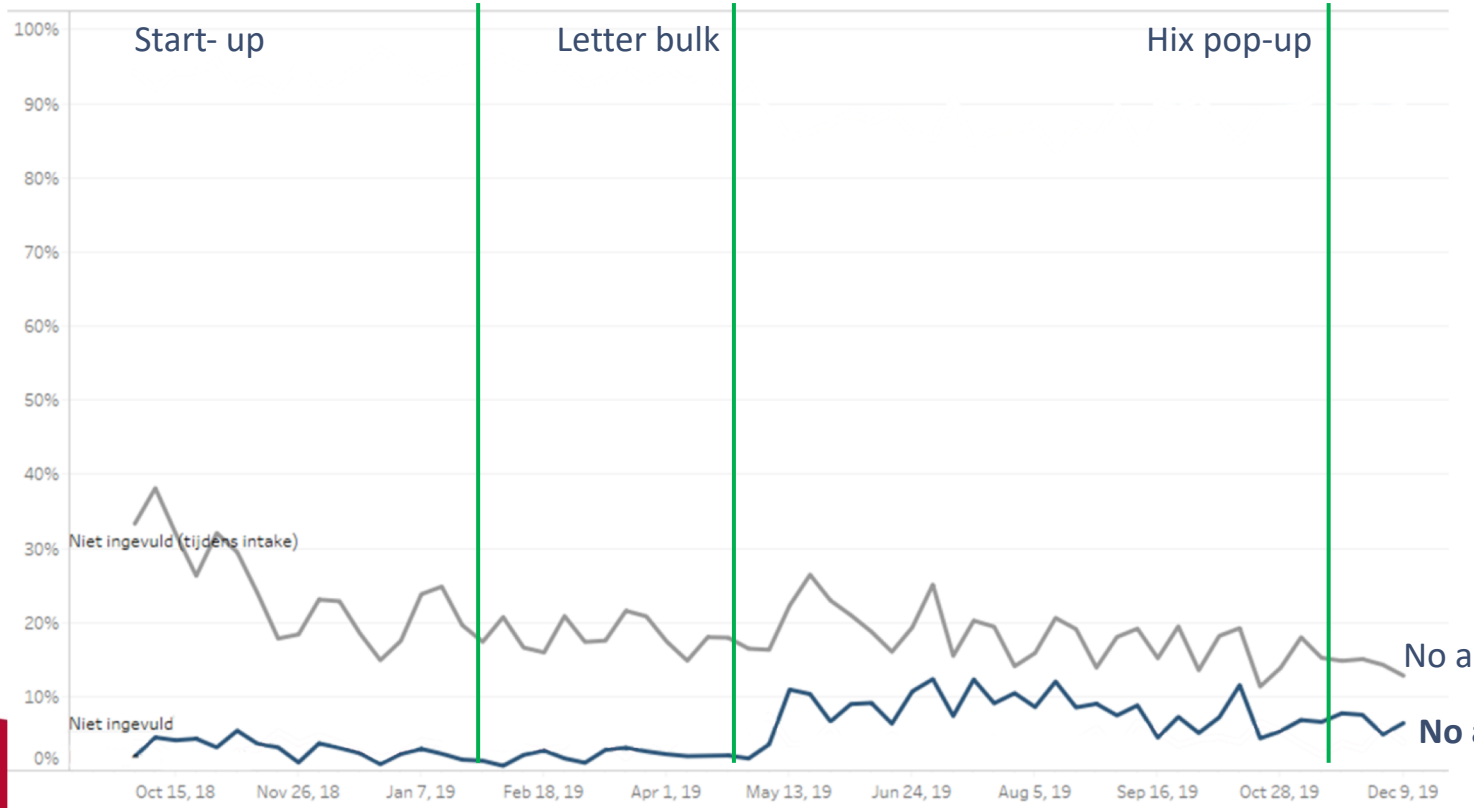

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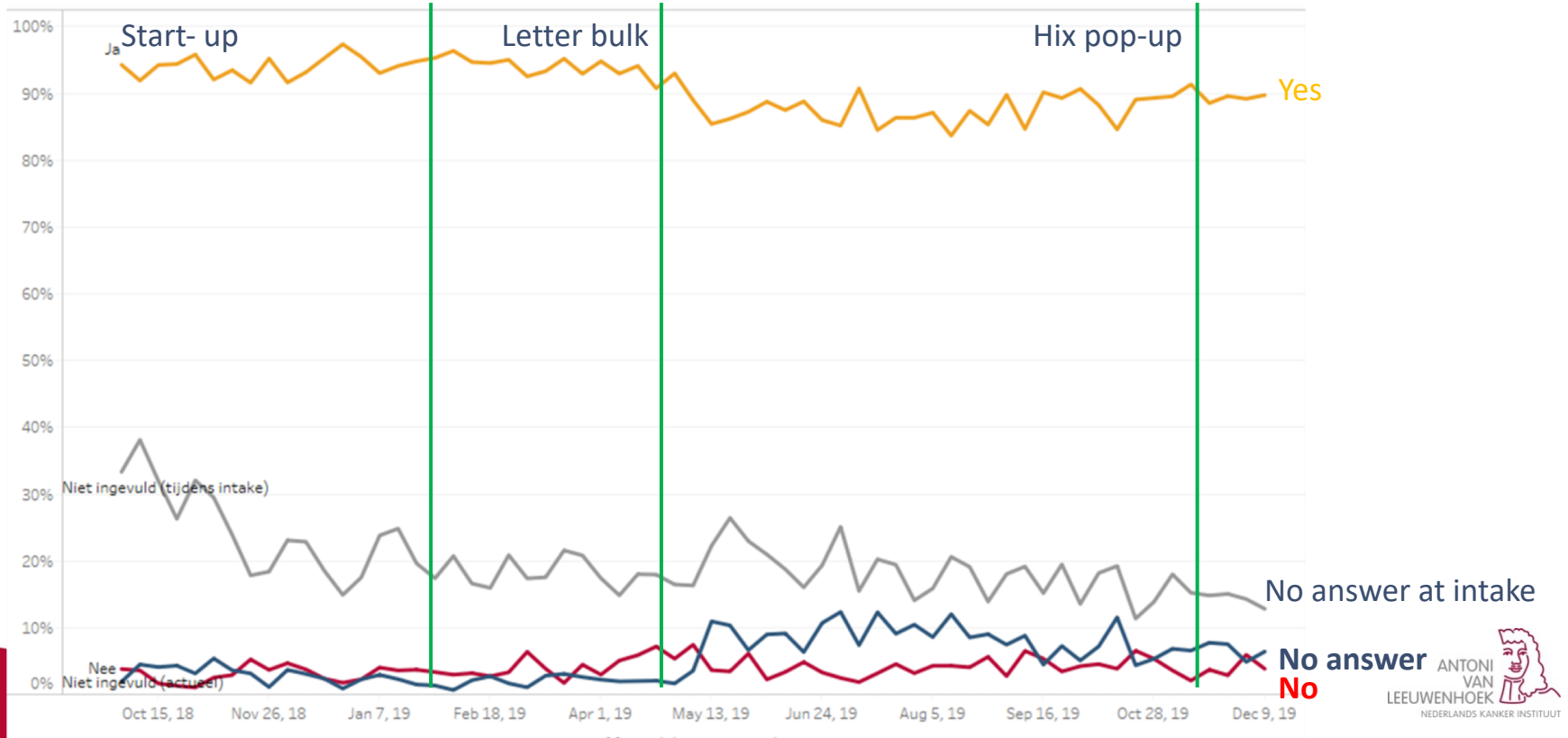
PROGRESS AND ANSWERS: ~90% YES, ~3% NO



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HOW PATIENTS PERCEIVED THE PROCEDURE

In start-up phase:

- 78 patients selected for interview (about 1/3 category)→ 64 participated
- 61% remembered their decision correctly
- Procedure appreciated by most patients

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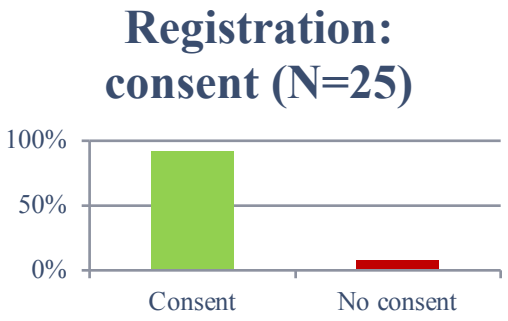
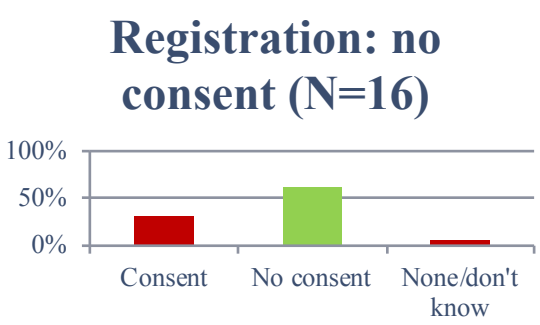
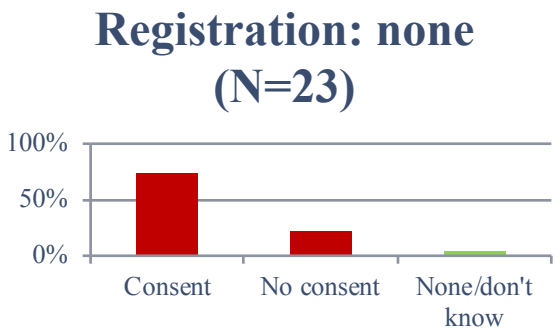
DID THEIR REGISTRATION MATCH THEIR WISHES?







PATIENT ARGUMENTS

- Consent:
  - To help further research / contribute to future patients' care
- No consent:
  - Too much on their minds to deal with the questions
  - Wrong timing/needed time to think
  - Fear of more paperwork etc.
  - Privacy (abroad)
- No decision
  - Usually not asked
  - Wrong timing/needed time to think/read brochure

GOAL AND FUTURE

- >95% consent
- Further improve procedure
  - Patient study (information needs)
  - Procedure in clinic

IMPLEMENTATION BROAD CONSENT?

- AVL is pioneering
- UMC's may follow (pilots)
- Implementation document

ELSI SERVICEDESK

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