Practical issues in health services research in Switzerland: Experience with an end-of-life study in cancer patients.

Klazien Matter-Walstra [1,2], Rita Achermann [3], Andrea Bordoni [4], Silvia Dehler [5], Gernot Jundt [6], Isabelle Konzelmann [7], Matthias Schwenkglenks [1], Bernhard C. Pestalozzi [8] on behalf of the Swiss Group for Clinical Cancer Research (SAKK)

1) Institute of Pharmaceutical Medicine (ECPM), University Basel , 2) Swiss Group for Clinical Cancer Research Coordination Center (SAKK), Bern, 3) formerly Helsana, 4) Cancer Registry Ticino, 5) Cancer Registry Zürich and Zug, University Hospital Zürich, 6) Cancer Registry Baselstadt and Baselland, University Hospital Basel, 7) Cancer Registry Valais, Sion, 8) President network outcomes research, SAKK / Department Oncology, University Hospital Zürich

Background

Cancer registries, health insurance companies and administrative bodies can contribute important data for health services research (HSR). However, using and combining data from different sources may be challenging.

Methods

We describe the process of activating an end-of-life patterns of care study in Swiss cancer patients deceased in 2006-2008 that were enrolled with one health insurance company (Helsana)

To identify cancer patients in the insurance data base, insurance and cancer registry data had to be combined.

In order to complement insurance-based inpatient information, medical records of hospitalized patients had to be reviewed for in-stay use of resources.

These data collection and linkage procedures gave rise to several complicated administrative issues that had to be resolved.

Results

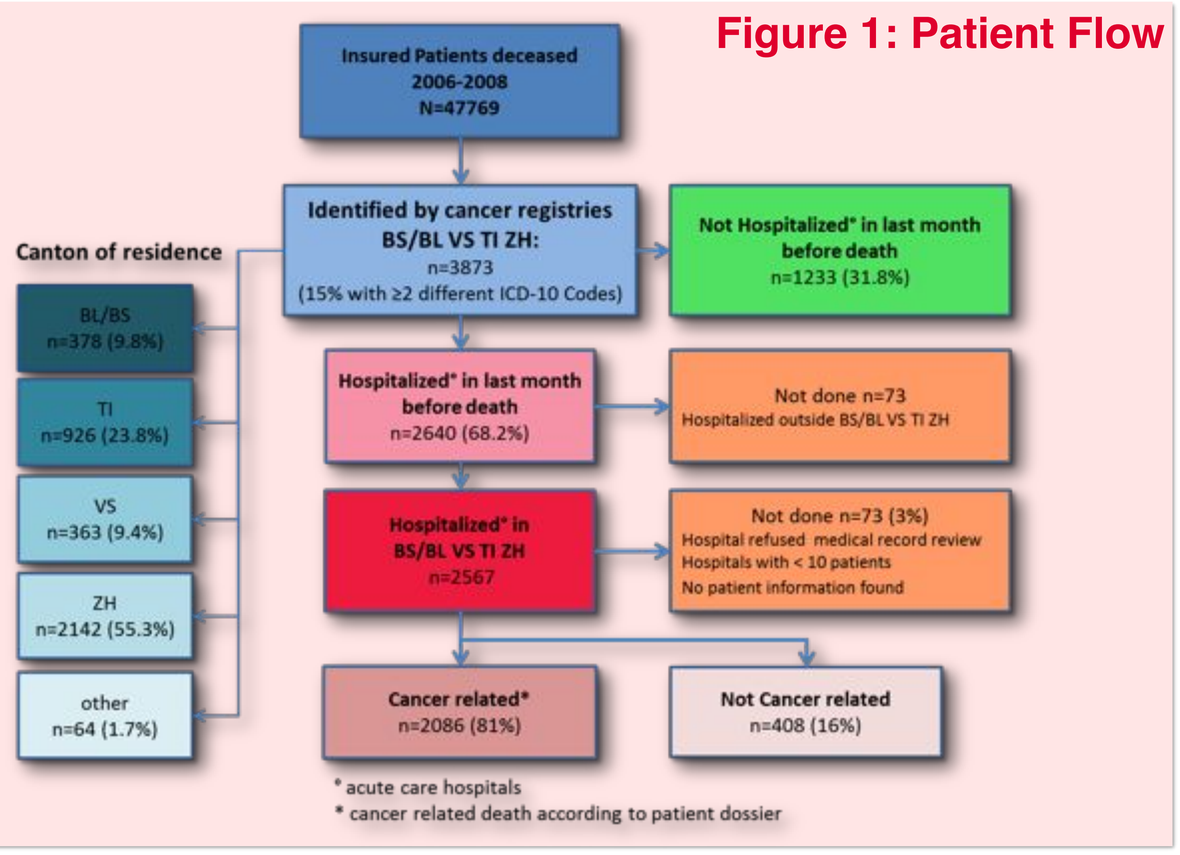
- In a first step the ethics committees and an advisory body of the Swiss Federal Office of Public Health had to decide on **responsibility for granting permission** to obtain and combine data. This process lasted almost one year. The time line of these procedures is shown in Table 1.
- The **identification of eligible patients** using cancer registry data from four cantons worked well even with diverse database structures.
- Retrieving details on **in-stay resource use** not available from the insurance database required additional approvals. We had to contact 49 hospitals and perform an extensive medical chart review. This applied to 68% of 3873 eligible patients; 94.5% of relevant hospitalization episodes were evaluated in 37 hospitals. The results are shown in Figure 1.

Table 1: Time-line of the End-of-Life study activation

Year	Involved parties	Study team	SAKK	Ethics Com	Expert Com	Cancer Reg	Helsana	Hospital	Action
	Month								
2008	September								Meeting Helsana and ECPM to discuss possible study
	December								**Study proposal to SAKK**
									Co-operation proposal to the Foundation National Institute for Cancer Epidemiology and Registration (NICER) and the Swiss cancer registries
2009	January-May								Co-operation agreed with cancer registries Basel (BS/BL), Valais (VS), Ticino (TI), Zürich (ZH)
									Study proposal accepted by SAKK
									Start study protocol development
	June								Request to receive a special permit for data disclosure (SPDD) sent to expert commission dealing with data protection issues (Expertenkommission zum Erhalt einer Sonderbewilligung) at the Federal office of Public Health (BAG)
	July								***Request to receive a SPDD objected by expert commission BAG, ethics committee (EC) approval requested first***
	August								Informal information by the legal expert of the EC in Basel (Ethikkomission beider Basel, EKBB) that he believes EC is not responsible, expert commission BAG has to authorize the study
	September								Letter to EKBB to ask whether to submit the study to EC or not.
	November								Answer EKBB: Request for authorization should be submitted. EKBB can be lead EC
	December								**Protocol finalized and signed by SAKK Board**
2010	February								Submission of study to leading EKBB and EC VS, EC TI, EC ZH
	March								Contact between legal expert EKBB and expert commission BAG on responsibility to authorize the study
	April								Invitation by the EKBB to explain study in more detail and answer questions
	May								Meeting with EKBB
									Answer EKBB: study needs adaptation
	June								Replay to EKBB concerning adaptation requests: study design is defended, requested adaptations are not considered scientifical valid
	July								**Positive approval decision by EKBB**
	August								**Positive approval decision by EC ZH, VS**
	September								Re-submission request to receive a SPDD to expert commission BAG
	October								**Positive approval decision by EC TI**
									Positive decision for SPDD by expert commission BAG
2011	January								**Data delivery Helsana**
			KFS						Submission grant application Cancer Research Switzerland (KFS)
	March- May								Data linkage BS/BL, VS, TI, ZH
	June								Final database delivery by Helsana for included patients
	July								Data analysis to identify patients with a hospitalization in last month before death (result see figure 1)
			KFS						**Grant application KFS approved**
	August-December								Complementation of Helsana database for missing informationn ambulatory care (last 3 month before death) by reviewing paper bills (Approximately 3500)
	November								Letter to hospitals (49) with request for reviewing patients medical records for in-stay data collection
2012	February								***Hospitals in Valais refuse insight in patient's medical records and request for extension of the SPDD to allow for data disclosure***
	March								Submission for extension of the SPDD tallow for collection of hospital data to expert commission BAG
									Approval of the extension of the SPDD
	January-July								Data collection in the hospitals
	September								Start data analysis

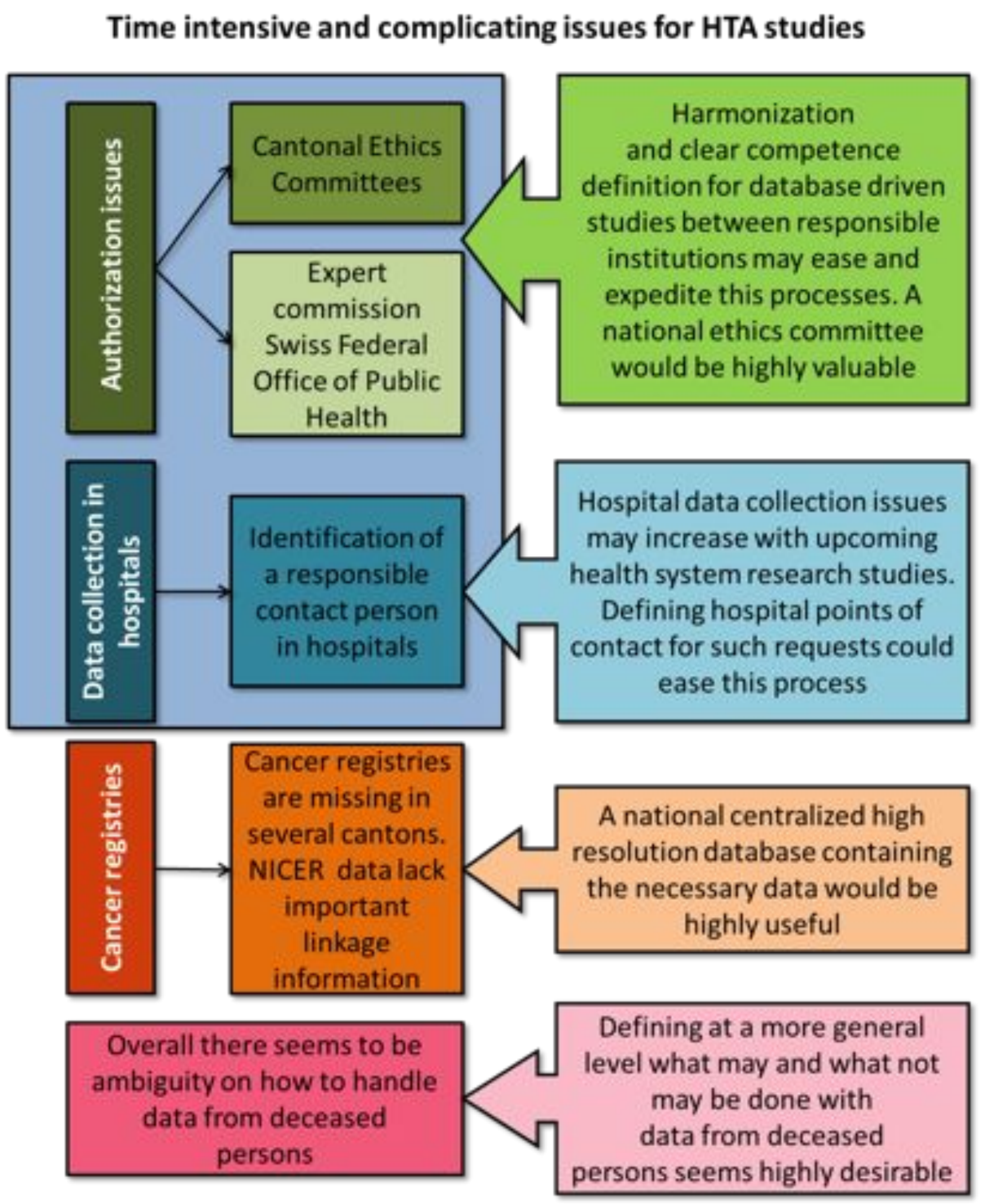
Acknowledgements:
We would like to thank all persons involved for their time, co-operation and encouragement.

Figure 1: Patient Flow



Cancer related death information is only systematically available for those patients who were subject to a medical chart review.

Discussion



Conclusion

HSR studies in Switzerland with large datasets are possible but need perseverance and may involve labor-intensive processes to complement lacking information.

As this type of study will become more common, simplifying and standardizing the process of obtaining permissions and data collection is necessary.

Email: klazien.matter@unibas.ch