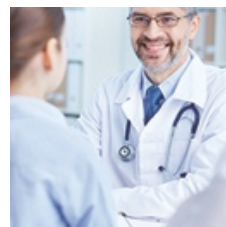


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# Oncology data landscape in Europe

Country profiles  
July 2018

A.T. Kearney

# Disclaimer

*The following research has been conducted by A.T. Kearney and IQVIA, and does not constitute an EFPIA position on health data in oncology.*



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# Executive summary

- \* This document outlines the **key characteristics and maturity level of health data in 10 European countries**
- \* We conducted a **landscape review and ~40 interviews** (16 internal interviews with oncology and RWD experts across 11 pharmaceutical companies and 22 external interviews across 8 countries)
- \* Each country has been rated **quantitatively and qualitatively** across **five characteristics: political, economic, societal, technical and legal**
- \* **Although most countries are embracing health data to some level, disparities exist in the ease of access and quality of data collected:**
  - **The Nordics and UK are the leading countries in Europe**, where national strategies and centralised health systems foster access, sharing and quality
  - Countries like the **Netherlands, France, Spain and others are developing their health data abilities**, but are either in early stages or facing some pushback
  - **Germany and Italy are lagging behind the rest of Europe**, where strict privacy rules and fragmented health systems impede collection and use of oncology health data



# Contents

 **Background & method**

 European overview

 Country profiles

# Each country has been rated qualitatively and quantitatively across the five identified barriers, using desk research and interviews

## Method for country profiling

### Quantitative analysis of country across key barriers

Health data profile: Belgium (1/2)		Health data profile: Belgium (2/2)	
* ranges low		* ranges low	
● ● ● ● ● low / medium / high		● ● ● ● ● low / medium / high	
<b>Political</b>	National eHealth policy or strategy	✓	Technical (cont.)
<b>Political</b>	National plan or policy to implement EHRs	✓	Interoperability & linkage
<b>Political</b>	National plan or policy for 2+ uses of data	✓	Use of unique identifying number for record linkage
<b>Political</b>	Implementation of national EHR	✓	Use of national data to record linkage projects
<b>Political</b>	Primary care facilities with EHR	70%	Specific rules & standards on EHR interoperability
<b>Political</b>	Specialist facilities with EHR	80%	Quality audits of EHR records
<b>Political</b>	Hospitals with EHR	75%	Certification that requires vendors to (1) adopt standards & (2) use structure data
<b>Economic</b>	Number of eHealth funding sources*	3/4	Incentives or penalties to support quality
<b>Economic</b>	Sum of eHealth funding amounts	100%	Legal
<b>Economic</b>	Driver of eHealth funding	25%	Specific rules on hosting & processing of EHRs
<b>Economic</b>	Public-private partnerships for eHealth	25%	Specific authorisation to host & process EHRs
<b>Societal</b>	Use of internet to search for health info.	56%	Legal requirement for encrypted data in EHRs
<b>Societal</b>	Knowledge of how to use health-related info. found online	88%	Specific rules for archiving duration of EHRs
<b>Societal</b>	Trust in health & medical bodies to protect data	88%	Specific law on 2+ uses of data
<b>Societal</b>	Health sciences students with pre-service training in eHealth	25%	Use of 2+ parties to (1) create (2) de-identify or (3) approve data requests for access
<b>Technical</b>	Quality of population-based cancer registries	✓	Legal rules on patient consent
<b>Technical</b>	Operational national cancer plans	✓	Rules on a patient's consent to create EHRs
<b>Technical</b>	Defined minimum dataset	✓	Rules on a patient's consent to share the EHR
<b>Technical</b>	Structuring of data elements	✓	Rules on identification & access of HCPs
<b>Technical</b>	Rules on common terminology for EHR	✓	Explicit prohibitions
<b>Legal</b>			Patient right to full access
<b>Legal</b>			Patient right to modify or erase data
<b>Legal</b>			Requirement for DPO (per-GDPR)
<b>Legal</b>			Breach notification requirement
<b>Legal</b>			Cyber security law

For each country, a **quantitative analysis** was conducted using desk research & stakeholder interviews, ranking countries across sub-categories, under the key barriers:

- 1 Political
- 2 Economic
- 3 Societal
- 4 Technical
- 5 Legal

### Qualitative analysis of country across key barriers

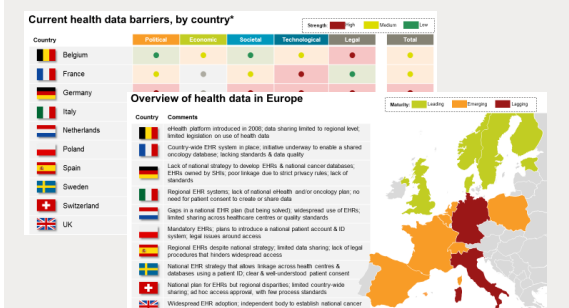
Health data profile: Belgium (1/2)		Health data profile: Belgium (2/2)	
* ranges low		* ranges low	
● ● ● ● ● low / medium / high		● ● ● ● ● low / medium / high	
<b>Political</b>	Deployment of shared EHRs since 2008	✓	Technical (cont.)
<b>Political</b>	Public health monitoring is not yet incorporated in EHR plans, but it is part of EHR functionality, patient safety monitoring is being considered as well, but the focus is on EHR deployment	✓	Interoperability & linkage
<b>Political</b>	An eHealth Platform was established in 2008 that sets standards for clinical terminology & interoperability, working groups develop standards & include representatives from PFG Public Health, the National Insurance Institute & other public health institutions	✓	Use of unique identifying number for record linkage
<b>Political</b>	Exchange of data is organised at a regional level, using a federal reference directory, unique patient identifying number & common standards to ensure interoperability & achieve national coverage	✓	Use of national data to record linkage projects
<b>Economic</b>	3 sources (public, private, PPP) provide most of the eHealth funding, though there is no donor / non-public funding	✓	Specific rules & standards on EHR interoperability
<b>Economic</b>	Public funding provides more than 75%	✓	Quality audits of EHR records
<b>Societal</b>	Patients are as likely to use the internet to search for health info (vs 59%) or know how to use it (vs 50%), & are more trusting (vs 74%), than patients in the EU	✓	Certification that requires vendors to (1) adopt standards & (2) use structure data
<b>Technical</b>	A minimum dataset was implemented in 2003 but 5% of patient records actually contain it	✓	Incentives or penalties to support quality
<b>Legal</b>	The identification number van de sociale zekerheid (INSZ) is the identifying number used for healthcare, social security & tax	✓	Legal
<b>Legal</b>	Data linkage is conducted by networks of hospitals & with 5-6 national databases using the INSZ	✓	Specific rules on hosting & processing of EHRs
<b>Legal</b>			Specific authorisation to host & process EHRs
<b>Legal</b>			Legal requirement for encrypted data in EHRs
<b>Legal</b>			Specific rules for archiving duration of EHRs
<b>Legal</b>			Specific law on 2+ uses of data
<b>Legal</b>			Use of 2+ parties to (1) create (2) de-identify or (3) approve data requests for access
<b>Legal</b>			Legal rules on patient consent
<b>Legal</b>			Rules on a patient's consent to create EHRs
<b>Legal</b>			Rules on a patient's consent to share the EHR
<b>Legal</b>			Rules on identification & access of HCPs
<b>Legal</b>			Explicit prohibitions
<b>Legal</b>			Patient right to full access
<b>Legal</b>			Patient right to modify or erase data
<b>Legal</b>			Requirement for DPO (per-GDPR)
<b>Legal</b>			Breach notification requirement
<b>Legal</b>			Cyber security law

For each country, a **qualitative analysis** was conducted using desk research & stakeholder interviews

Case study examples are used to outline the landscape in each country, under the five key barriers

Where possible, **country-specific names** have been included in the analysis

### Country mapping by barrier & overall data landscape




For each country, an overall ranking has been outlined covering:

1. **Severity of the barriers** (high – low)
2. **Overall health data landscape** including key features (leading – emerging – lagging)



## Contents

 Background & method

 **European overview**

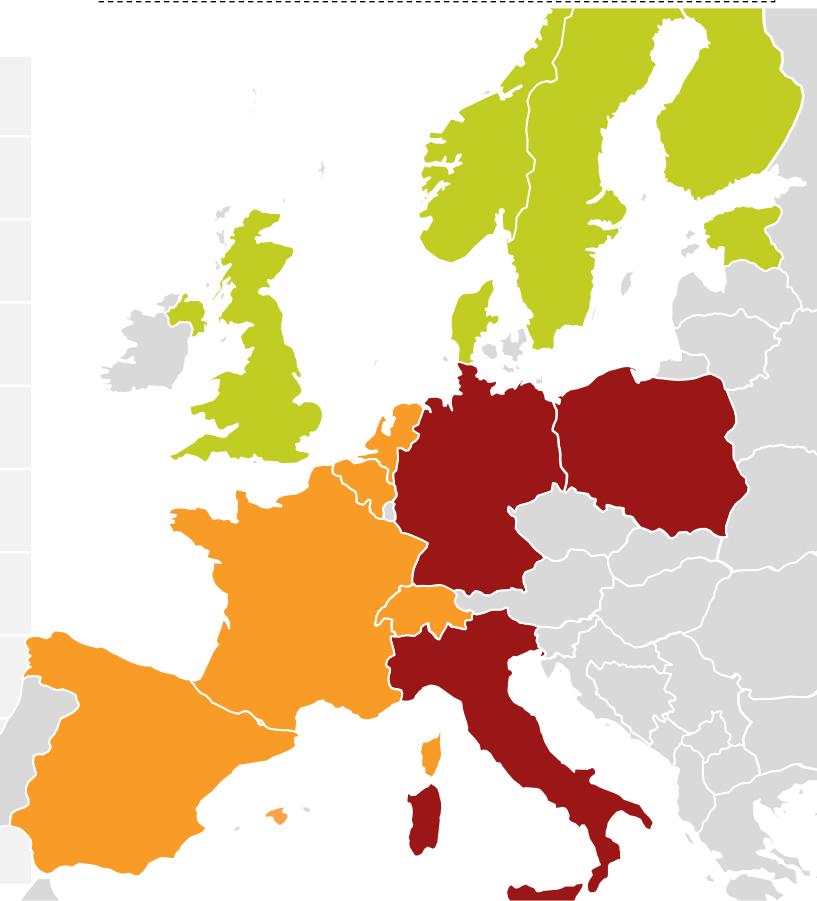
 Country profiles

# Scandinavian countries have the most advanced EHR systems; other countries face significant legal and political barriers

## Overview of health data in Europe



Country	Comments
	eHealth platform introduced in 2008; data sharing limited to regional level; limited legislation on use of health data
	Country-wide EHR system in place; initiative underway to enable a shared oncology database; lacking standards & data quality
	EHRs owned by SHIs; poor linkage due to strict privacy rules; lack of standards
	Regional EHR systems; lack of national eHealth and/or oncology plan; several managed-entry agreements in place for new oncology drugs
	Gaps in a national EHR plan (but being solved); widespread use of EHRs; limited sharing across healthcare centres or quality standards
	Mandatory EHRs; plans to introduce a national patient account & ID system; legal issues around access
	Regional EHRs despite national strategy; limited data sharing; lack of legal procedures that hinders widespread access
	National EHR strategy that allows linkage across health centres & databases using a patient ID; clear & well-understood patient consent
	National plan for EHRs but regional disparities; limited country-wide sharing; ad hoc access approval, with few process standards
	Widespread EHR adoption; independent body to establish national cancer databases; well-developed data quality & linkage across datasets



EHR = electronic health records; SHI = social health insurer;  
 Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OECD "Health Data Governance"; External interviews; A.T. Kearney analysis; IQVIA analysis















# Legal and technological barriers are significant for several European countries; political barriers are slowly improving

## Current health data barriers, by country\*



Country	Political	Economic	Societal	Technological	Legal	Total
 Belgium	●	●	●	●	●	●
 France	●	●	●	●	●	●
 Germany	●	●	●	●	●	●
 Italy	●	●	●	●	●	●
 Netherlands	●	●	●	●	●	●
 Poland	●	●	●	●	●	●
 Spain	●	●	●	●	●	●
 Sweden	●	●	●	●	●	●
 Switzerland	●	●	●	●	●	●
 UK	●	●	●	●	●	●

\*Limited data for certain countries means that analysis of some barriers is inconclusive  
 Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OECD "Health Data Governance"; External interviews; A.T. Kearney analysis; IQVIA analysis



# Legal and technological barriers are significant for several European countries; political barriers are slowly improving

## Health data profile overview (1/2)

✓ x = yes / no      ● ● ● = low / medium / high

<b>Political</b>											
eHealth national strategy	National eHealth policy or strategy	✓	✓	✓	x	✓	✓	x	✓	✓	✓
	National plan or policy to implement EHRs	✓	✓	x	-	x	✓	✓	x	✓	✓
	National plan or policy inc. 2° uses of data	✓	✓	-	-	-	✓	x	-	x	✓
EHR systems	Implementation of national EHR	✓	✓	x	✓	x	✓	✓	✓	✓	✓
	Primary care facilities with EHR	70%	N/A	80%	100%	100%	15%	90%	100%	20%	100%
	Specialist facilities with EHR	80%	N/A	80%	-	100%	10%	25%	100%	-	20%
	Hospitals with EHR	75%	N/A	90%	-	100%	5%	70%	100%	90%	100%
<b>Economic</b>											
Provision of funding	Number of eHealth funding sources*	3/4	N/A	N/A	4/4	4/4	2/4	4/4	2/4	3/4	2/4
	Sum of eHealth funding amounts	100%	N/A	N/A	100%	100%	100%	100%	100%	75%	100%
	Driver of eHealth funding	Public	N/A	N/A	Public	Public	Public	Public	Public	PrivPub	Public
	Public-private partnerships for eHealth	25%	N/A	N/A	25%	25%	0%	25%	25%	25%	25%
<b>Societal</b>											
Patient trust & autonomy	Use of Internet to search for health info.	56%	63%	57%	59%	73%	60%	55%	70%	-	60%
	Knowledge of how to use health-related info. found online	88%	87%	87%	87%	91%	93%	90%	94%	-	95%
	Trust in health & medical bodies to protect data	85%	79%	77%	64%	81%	61%	74%	88%	-	81%
Training in eHealth	Health sciences students with pre-service training in eHealth	25%	-	-	25%	63%	63%	25%	75%	25%	38%
	HCPs with in-service training in eHealth	25%	-	-	63%	63%	38%	38%	75%	75%	63%
<b>Technical</b>											
Disease complex.	Quality of population-based cancer registries	●	●	●	●	●	●	●	●	●	●
	Operational national cancer plans	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Definition & standards	Defined minimum dataset	✓	x	x	-	x	✓	✓	✓	✓	✓
	Structuring of data elements	●	●	●	-	●	●	●	●	●	●
	Rules on common terminology for EHR	x	x	x	✓	x	✓	✓	✓	x	✓

EHR=electronic medical record; HCP=healthcare professional; PPP=public-private partnership; \*Public, private / commercial, donor / non-public or PPP

Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OECD 'Health Data Governance'; External interviews; A.T. Kearney analysis; IQVIA analysis

# Legal and technological barriers are significant for several European countries; political barriers are slowly improving

## Health data profile overview (2/2)

✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)											
Interoperability & linkage	Electronic sharing of information about patients	✓	✓	✓	-	✓	x	✓	✓	✓	✓
	Use of unique identifying number for record linkage*	6/10	5/10	3/10	-	-	4/10	-	7/10	3/10	10/10
	Use of national data to record linkage projects*	7/10	4/10	0/10	-	-	0/10	-	7/10	5/10	9/10
	Specific rules & standards on EHR interoperability	✓	x	x	✓	x	✓	✓	✓	-	x
Quality assurance	Quality audits of EHR records	✓	x	x	-	x	x	✓	x	✓	✓
	Certification that requires vendors to (1) adopt standards & (2) use structure data	✓✓	✓✓	✓	-	x	x	x	✓	x	✓
	Incentives or penalties to support quality	●	●	●	-	●	●	●	●	●	●
<b>Legal</b>											
Hosting & processing	Specific rules on hosting & processing of EHRs	x	✓	x	x	x	✓	✓	✓	-	✓
	Specific authorisation to host & process EHRs	x	✓	✓	x	x	x	x	x	-	✓
	Legal requirement for encrypted data in EHRs	x	x	x	✓	x	✓	x	x	-	x
	Specific rules for archiving duration of EHRs	x	✓	x	x	x	x	x	x	-	x
	Specific law on 2° use of data	x	✓	x	✓	✓	✓	✓	✓	-	✓
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	2/3	2/3	3/3	-	3/3	3/3	3/3	3/3	3/3	-
Patient consent	Legal rules on patient consent	✓	✓	✓	✓	x	x	✓	✓	-	✓
	Rules on a patient's consent to create EHRs	x	✓	✓	x	x	x	x	✓	-	✓
	Rules on a patient's consent to share the EHR	x	✓	x	x	✓	x	x	✓	-	✓
Access & update of EHRs	Rules on identification & access of HCPs	✓	✓	✓	✓	x	✓	✓	✓	-	✓
	Explicit prohibitions	✓	✓	x	✓	✓	x	x	x	-	x
	Patient right to full access	✓	x	✓	✓	✓	✓	✓	x	-	x
	Patient right to modify or erase data	x	✓	✓	✓	✓	x	x	x	-	x
Data protection	Requirement for DPO (pre-GDPR)	x	x	✓	x	x	x	x	x	x	x
	Breach notification requirement	x	x	✓	✓	✓	✓	✓	✓	x	✓
	Cyber security law	x	✓	✓	x	x	x	x	x	x	x




EHR=electronic medical record; DPO=data protection officer; HCP=healthcare professional ; \*Out of 10 types of data that can be linked

Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OECD

'Health Data Governance'; External interviews; A.T. Kearney analysis; IQVIA analysis



## Contents

-  Introduction
-  European overview
-  **Country profiles**



# Belgium is rapidly developing its health data infrastructure and making efforts to standardise, though legal barriers remain

## Health data profile: Belgium (1/2)



✓ x = yes / no      ● ● ● = low / medium / high

Political		
eHealth national strategy	National eHealth policy or strategy	✓
	National plan or policy to implement EHRs	✓
	National plan or policy inc. 2° uses of data	✓
EHR systems	Implementation of national EHR	✓
	Primary care facilities with EHR	70%
	Specialist facilities with EHR	80%
	Hospitals with EHR	75%
Economic		
Provision of funding	Number of eHealth funding sources*	3/4
	Sum of eHealth funding amounts	100%
	Driver of eHealth funding	Public
	Public-private partnerships for eHealth	25%
Societal		
Patient trust & autonomy	Use of Internet to search for health info.	56%
	Knowledge of how to use health-related info. found online	88%
	Trust in health & medical bodies to protect data	85%
Training in eHealth	Health sciences students with pre-service training in eHealth	25%
	HCPs with in-service training in eHealth	25%
Technical		
Disease complex.	Quality of population-based cancer registries	●
	Operational national cancer plans	✓
Definition & standards	Defined minimum dataset	✓
	Structuring of data elements	●
	Rules on common terminology for EHR	x

- Deployment of **shared EHRs since 2008**
- Public health monitoring is not yet incorporated in EHR plans, but it is part of EHR functionality; **patient safety monitoring** is being considered as well, but the focus is on EHR deployment
- An **eHealth Platform** was established in 2008 that sets **standards for clinical terminology & interoperability**; working groups develop standards & include representatives from PFS Public Health, the National Insurance Institute & other public health institutions
- **Exchange of data** is organised at a **regional level**, using a federal reference directory, **unique patient identifying number** & common standards to ensure interoperability & achieve national coverage

- 3 sources (public, private, PPP) provide most of the eHealth funding, though there is no donor or non-public funding
- **Public funding** provides more than 75%

- Patients are **as likely to use the Internet** to search for health info (vs 59%) or know how to use it (vs 90%), & are more trusting (vs 74%), than average patients in the EU

- A **minimum dataset** was implemented in 2003 but 5% of patient records actually contain it
- The **'identificatienummer van de sociale zekerheid' (INSZ)** is the identifying number used for healthcare, social security & tax
- Data linkage is conducted by **networks of hospitals** & with **5-6 national databases** using the INSZ



# Belgium is rapidly developing its health data infrastructure and making efforts to standardise, though legal barriers remain

## Health data profile: Belgium (2/2)



✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	✓
	Use of unique identifying number for record linkage*	6/10
	Use of national data to record linkage projects*	7/10
	Specific rules & standards on EHR interoperability	✓
Quality assurance	Quality audits of EHR records	✓
	Certification that requires vendors to (1) adopt standards & (2) use structure data	✓✓
	Incentives or penalties to support quality	●
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	x
	Specific authorisation to host & process EHRs	x
	Legal requirement for encrypted data in EHRs	x
	Specific rules for archiving duration of EHRs	x
	Specific law on 2° use of data	x
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	2/3
Patient consent	Legal rules on patient consent	✓
	Rules on a patient's consent to create EHRs	x
	Rules on a patient's consent to share the EHR	x
Access & update of EHRs	Rules on identification & access of HCPs	✓
	Explicit prohibitions	✓
	Patient right to full access	✓
	Patient right to modify or erase data	x
Data protection	Requirement for DPO (pre-GDPR)	x
	Breach notification requirement	x
	Cyber security law	x

- **Cancer registry** data is linked to mortality data, to health insurance nomenclature, to hospital in-patient data & to cancer screening
  - As a result of the legislation specific to the cancer registry, the **Commission for the Protection of Privacy (CPP) has approved** the cancer registry to **collect** identifiable personal health data, **link** the data & then to **conduct analysis** of de-identified data
- In general, data linkage takes place **within the E-health Platform**, as a third party authorised by law to access/use identifiable health data & that is trusted to undertake data linkages that are approved by the CPP

- 2° uses of data include **general research & scientific purpose, statistics & historical purpose**
- The CPP grants authority to **collect & use identifiable personal information without consent**, & approves **data linkage projects** – only **de-identified data** is provided to governmental & non-governmental researchers for analysis
- After the **introduction of the EU Data Protection Directive**, the CPP advised the **cancer registry that it could no longer process** identifiable personal health data & that the only way to continue normal operations would be to draft authorising legislation & reapply for permission;
  - The legislation authorising the cancer registry now clarifies that **patient consent is not required** to create the registry, link or analyse the data
  - This took time & the **quality of the registry** suffered
- **No specific breach notification rules** exists, but **guidance is given** to companies to notify in the case of “**public incidents**”

EHR=electronic medical record; DPO=data protection officer; HCP=healthcare professional ; \*Out of 10 types of data that can be linked

Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OECD

'Health Data Governance'; External interviews; A.T. Kearney analysis; IQVIA analysis

# France shows mature adoption of EHRs allowing sharing, but technical barriers impact quality and standards

## Health data profile: France (1/2)



✓ x = yes / no      ● ● ● = low / medium / high

Political		
eHealth national strategy	National eHealth policy or strategy	✓
	National plan or policy to implement EHRs	✓
	National plan or policy inc. 2° uses of data	✓
EHR systems	Implementation of national EHR	✓
	Primary care facilities with EHR	N/A
	Specialist facilities with EHR	N/A
	Hospitals with EHR	N/A
Economic		
Provision of funding	Number of eHealth funding sources*	N/A
	Sum of eHealth funding amounts	N/A
	Driver of eHealth funding	N/A
	Public-private partnerships for eHealth	N/A
Societal		
Patient trust & autonomy	Use of Internet to search for health info.	63%
	Knowledge of how to use health-related info. found online	87%
	Trust in health & medical bodies to protect data	79%
Training in eHealth	Health sciences students with pre-service training in eHealth	-
	HCPs with in-service training in eHealth	-
Technical		
Disease complex.	Quality of population-based cancer registries	●
	Operational national cancer plans	✓
Definition & standards	Defined minimum dataset	x
	Structuring of data elements	●
	Rules on common terminology for EHR	x

- Deployment of **shared EHRs since 2006**
- A **collaborative project** between the **National Institute for Cancer & Agence des Systemes d'Information Partages de Sante (ASIP Santé)** is underway to build a database for **shared oncology records** with a single custodian
- The **national cancer plan ('Plan Cancer 2014-2019')** has a full chapter dedicated to the use of robust & shared data, to better understand care pathways & inequalities, & have a strong observational system in place
- The **ASIP Sante**, representing industry, patients, legal & health professionals, took responsibility for **setting all operability standards & agreements** with data custodians in 2009
- Exchange of data is permitted via implementation of a **country-wide EHR system**

- Patients are **as likely to use the Internet** to search for health info (vs 59%), or know how to use it (vs 90%), & are more trusting (vs 74%), than average patients in the EU

- There are **no minimum datasets & patients specify the elements** of the EHRs to be shared
- The 'numéro d'identification au répertoire' (NIR) is used for **medical insurance**, but is **different from the numbers** used for **linkage across hospitals**; discussions are underway to use a 3<sup>rd</sup> party to link these together
- Data linkage is conducted with **5-6 databases using the NIR**

# France shows mature adoption of EHRs allowing sharing, but technical barriers impact quality and standards

## Health data profile: France (2/2)



✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	✓
	Use of unique identifying number for record linkage*	5/10
	Use of national data to record linkage projects*	4/10
	Specific rules & standards on EHR interoperability	x
Quality assurance	Quality audits of EHR records	x
	Certification that requires vendors to (1) adopt standards & (2) use structure data	✓✓
	Incentives or penalties to support quality	●
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	✓
	Specific authorisation to host & process EHRs	✓
	Legal requirement for encrypted data in EHRs	x
	Specific rules for archiving duration of EHRs	✓
	Specific law on 2° use of data	✓
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	2/3
Patient consent	Legal rules on patient consent	✓
	Rules on a patient's consent to create EHRs	✓
	Rules on a patient's consent to share the EHR	✓
Access & update of EHRs	Rules on identification & access of HCPs	✓
	Explicit prohibitions	✓
	Patient right to full access	x
	Patient right to modify or erase data	✓
Data protection	Requirement for DPO (pre-GDPR)	x
	Breach notification requirement	x
	Cyber security law	✓

- In general, France has invested in **methods for the de-identification** of data, using a **hashing algorithm** that converts names to a numerical code that cannot be reversed
- Codes are used to build **longitudinal health histories**, but given the need to verify content in health records for research studies, France has since developed a **reversible hashing algorithm**

- French law protects the **privacy & security of private health information**; consideration in the law for 2° uses cover **general research / scientific purposes**
- The 'Commission Nationale de l'Information et des Libertés' (CNIL) is a data protection authority that **authorises access on a case-by-case basis** for projects requiring access to health data
- Considerations include: **legality** of request; **legitimacy** of researchers; **affiliations** with credible organisations & use of **security measures**
- The **CNIL** may approve sharing of data to **another EU country**
- **Non-government researchers** must also be approved by 'le Comité du Secret statistique' of the '**Conseil national de l'information statistique** (CNIS)
- A French law came into affect in 2004 that stipulates HCPs must refer to EHRs where in place & **commit to completing** them according to **clinical terminology & interoperability standards**

EHR=electronic medical record; DPO=data protection officer; HCP=healthcare professional; \*Out of 10 types of data that can be linked

Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OECD

'Health Data Governance'; External interviews; A.T. Kearney analysis; IQVIA analysis

# Germany lacks a national approach to EHRs and technical barriers limit sharing, linkage and use of data for research

## Health data profile: Germany (1/2)



✓ x = yes / no      ● ● ● = low / medium / high

Political		
eHealth national strategy	National eHealth policy or strategy	✓
	National plan or policy to implement EHRs	x
	National plan or policy inc. 2° uses of data	-
EHR systems	Implementation of national EHR	x
	Primary care facilities with EHR	80%
	Specialist facilities with EHR	80%
	Hospitals with EHR	90%
Economic		
Provision of funding	Number of eHealth funding sources*	N/A
	Sum of eHealth funding amounts	N/A
	Driver of eHealth funding	N/A
	Public-private partnerships for eHealth	N/A
Societal		
Patient trust & autonomy	Use of Internet to search for health info.	57%
	Knowledge of how to use health-related info. found online	87%
	Trust in health & medical bodies to protect data	77%
Training in eHealth	Health sciences students with pre-service training in eHealth	-
	HCPs with in-service training in eHealth	-
Technical		
Disease complex.	Quality of population-based cancer registries	●
	Operational national cancer plans	✓
Definition & standards	Defined minimum dataset	x
	Structuring of data elements	●
	Rules on common terminology for EHR	x

- Currently there are **no national, shared EHR systems**; some initiatives are underway to change this
- A government plan to introduce the electronic health card in 2006 was **delayed to 2015** due to **physicians' concerns around privacy**
- The national cancer plan mandates the contribution to a national cancer registry funded by SHIs; each state then sends oncology data to the **Centre for Cancer Registry data** at the Robert Koch institute on an annual basis; the data is screened for completeness & **analysis is shared at a national level**
- **Gematik** is a healthcare provider organisation that sets out to establish a **national telematics infrastructure** & provides **guidance on the implementation** of interoperable documentation systems

• N/A

- Patients are **as likely to use the Internet** to search for health info (vs 59%) or know how to use it (vs 90%), & are more trusting (vs 74%), than patients in the EU

- **No minimum datasets are defined nationally**, with definition specific to care situation implemented by organisations of HCPs
- Data linkage is **not conducted at the national level** but at the **state level** in some states: Bremen, Hessen, Augsburg & Essen, where authorised by law
- **Legislation differs for cancer registries** to identify which information may be used to record linkage
- SHIs such as Barmer-GEK & AOK also **conduct linkage of data**



# Germany lacks a national approach to EHRs and technical barriers limit sharing, linkage and use of data for research

## Health data profile: Germany (2/2)



✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	✓
	Use of unique identifying number for record linkage*	3/10
	Use of national data to record linkage projects*	0/10
	Specific rules & standards on EHR interoperability	x
Quality assurance	Quality audits of EHR records	x
	Certification that requires vendors to (1) adopt standards & (2) use structure data	✓
	Incentives or penalties to support quality	●
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	x
	Specific authorisation to host & process EHRs	✓
	Legal requirement for encrypted data in EHRs	x
	Specific rules for archiving duration of EHRs	x
	Specific law on 2° use of data	x
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	3/3
Patient consent	Legal rules on patient consent	✓
	Rules on a patient's consent to create EHRs	✓
	Rules on a patient's consent to share the EHR	x
Access & update of EHRs	Rules on identification & access of HCPs	✓
	Explicit prohibitions	x
	Patient right to full access	✓
	Patient right to modify or erase data	✓
Data protection	Requirement for DPO (pre-GDPR)	✓
	Breach notification requirement	✓
	Cyber security law	✓

- Names, addresses & date of births are available, but **place of birth is not universally available** for probabilistic record linkage
- All German states can use the same **pseudonymisation algorithm** to render names anonymous, thus making it possible to **merge records at the Centre for Cancer Registry data** & correct for **biases due to patient mobility**
- Health insurance number** is mandatory & used for **data exchange**
- Personal health information can only be used for **original intended purposes** & e-Health data is collected for **medical care; no other 2° purposes** are specified in German law
- Explicit **allowances can be made possible** by law (e.g. for billing, monitoring or healthcare quality) to access health record data
- Researchers can access only **de-identified data from cancer registries**; some identifiers may be approved to remain on file (e.g. date & place of birth) if there is justification for inclusion – the decision depends of **re-identification risk**
- The Centre for Cancer Registry Data** makes data available for **research purposes to external scientists** through a scientific-use file, but any amalgamation of data from a state's research projects, especially the **linkage of cancer registries to other data sources**, requires **state approval**
- Data protection laws** are established at the **Federal & Land level**
- Each of the 16 German states has a **State Data Protection Commissioner** who is responsible for **service providers of the social security administration** at the state level
- Data subjects & regulators **must be notified** of data breaches if the breach involves **particularly sensitive data** (e.g. health data)



# Italy has a fragmented EHR landscape across regions, but coding standards are intended to support linkage at the national level

## Health data profile: Italy (1/2)



✓ x = yes / no      ● ● ● = low / medium / high

Political			
eHealth national strategy	National eHealth policy or strategy	x	
	National plan or policy to implement EHRs	-	
	National plan or policy inc. 2° uses of data	-	
EHR systems	Implementation of national EHR	✓	
	Primary care facilities with EHR	100%	
	Specialist facilities with EHR	-	
Economic	Hospitals with EHR	-	
	Number of eHealth funding sources*	4/4	
	Sum of eHealth funding amounts	100%	
	Driver of eHealth funding	Public	
Societal	Public-private partnerships for eHealth	25%	
	Patient trust & autonomy	Use of Internet to search for health info.	59%
		Knowledge of how to use health-related info. found online	87%
		Trust in health & medical bodies to protect data	64%
Training in eHealth	Health sciences students with pre-service training in eHealth	25%	
	HCPs with in-service training in eHealth	63%	
Technical			
Disease complex.	Quality of population-based cancer registries	●	
	Operational national cancer plans	✓	
Definition & standards	Defined minimum dataset	-	
	Structuring of data elements	-	
	Rules on common terminology for EHR	✓	

- Italy is currently in the **deployment phase of an EHR system at regional & autonomous province levels**
  - Certain regions & hospitals have good datasets e.g. **in Lombardia**, but they are **not uniform or centralised** at a national level
- Across the 19 territories & 2 provinces in Italy, each with local health authorities, it is **difficult to use regional data** as each region requires a different proposal & different requirements for approval
- The **Italian Medicines Agency (AIFA)** supports numerous managed-entry agreements for new oncology drugs, either as coverage requiring evidence development and/or outcomes-based schemes entailing collection of data to determine coverage
- 4 sources (public, private, PPP, donor) provide eHealth funding
- Public funding** provides more than 75% of eHealth funding
- Patients are **as likely to use the Internet** to search for health info (vs 59%) or know how to use it (vs 90%), & are less trusting (vs 74%), than average patients in the EU
- HCPs are provided with eHealth education programmes** that specifically offer training in digital & data analytics
- It is stipulated that EHR information should be **codified & classified** to ensure **interoperability at the regional, national & European level**; an annex to this draft sets out **codification & classification rules**
  - However, this Decree is still in a **draft phase**
- Data across **1-2 key national datasets** is linked for **statistical analysis & research purposes**

# Italy has a fragmented EHR landscape across regions, but coding standards are intended to support linkage at the national level

## Health data profile: Italy (2/2)



✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	-
	Use of unique identifying number for record linkage*	-
	Use of national data to record linkage projects*	-
	Specific rules & standards on EHR interoperability	✓
Quality assurance	Quality audits of EHR records	-
	Certification that requires vendors to (1) adopt standards & (2) use structure data	-
	Incentives or penalties to support quality	-
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	x
	Specific authorisation to host & process EHRs	x
	Legal requirement for encrypted data in EHRs	✓
	Specific rules for archiving duration of EHRs	x
	Specific law on 2° use of data	✓
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	-
Patient consent	Legal rules on patient consent	✓
	Rules on a patient's consent to create EHRs	x
	Rules on a patient's consent to share the EHR	x
Access & update of EHRs	Rules on identification & access of HCPs	✓
	Explicit prohibitions	✓
	Patient right to full access	✓
	Patient right to modify or erase data	✓
Data protection	Requirement for DPO (pre-GDPR)	x
	Breach notification requirement	✓
	Cyber security law	x

- The TS number links a **health & tax file number** with **coverage across most of the population** & managed through a privately-owned company, **Società Generale d'Informatica (SOGEI)**, a company 100% controlled by the Ministry of Economy & Finance that perform IT services for public administration services

- Many Italian regions have legislation that allows them to develop disease registries from health data **without patient consent** & to use the data for **research purposes** (consent is necessary otherwise)
- In Italian law, EHRs are established also for **medical & epidemiological research, & health service planning & evaluation**, but not for statistical analysis
- The **Privacy Guarantor** (the data protection authority) passed a general authorisation in 2011 to allow regions to **process identifiable & sensitive data for research purposes**
- A national-level registry **requires its own legislative approval** by the data protection authority to be used for research purposes; there are **concerns** that regional approval to use & analyse personal registry data could be **revoked by the Privacy Guarantor** in the wake of privacy concerns
- In 2004, Italy introduced a **Data Protection Code** including a section on the topic of **data processing in the health sector**; the code permits **processing of identifiable & sensitive personal health data** if the data subject has given **consent** (or if law authorises the process)
- Where breaches take place, publicly available electronic service providers must **notify the national regulators & data subjects**

EHR=electronic medical record; DPO=data protection officer; HCP=healthcare professional ; \*Out of 10 types of data that can be linked

Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OECD 'Health Data Governance'; External interviews; A.T. Kearney analysis; IQVIA analysis

# Use of EHRs is widespread, but sharing across healthcare providers is uncommon and linkage attempts were shut down

## Health data profile: Netherlands (1/2)



✓ x = yes / no      ● ● ● = low / medium / high

Political		
eHealth national strategy	National eHealth policy or strategy	✓
	National plan or policy to implement EHRs	x
	National plan or policy inc. 2° uses of data	-
EHR systems	Implementation of national EHR	x
	Primary care facilities with EHR	100%
	Specialist facilities with EHR	100%
	Hospitals with EHR	100%
Economic		
Provision of funding	Number of eHealth funding sources*	4/4
	Sum of eHealth funding amounts	100%
	Driver of eHealth funding	Public
	Public-private partnerships for eHealth	25%
Societal		
Patient trust & autonomy	Use of Internet to search for health info.	73%
	Knowledge of how to use health-related info. found online	91%
	Trust in health & medical bodies to protect data	81%
Training in eHealth	Health sciences students with pre-service training in eHealth	63%
	HCPs with in-service training in eHealth	63%
Technical		
Disease complex.	Quality of population-based cancer registries	●
	Operational national cancer plans	✓
Definition & standards	Defined minimum dataset	x
	Structuring of data elements	●
	Rules on common terminology for EHR	x

- A shared EHR system was deployed in 2011 but was later **legally closed**; other initiatives have been started to fill the gap:
  - The **Association of healthcare Providers** has stepped in to establish an EHR system that allows **exchange between regions**; without government involvement; this association **consults with patient associations** on the plans for the system
  - The **National IT Institute for healthcare (NICITZ)** develops **national standards** for e-communications
  - The **Quality of Care Institute** stimulates the **development of clinical guidelines**
- **Virtually all hospitals use EHRs**, but sharing between hospitals & physicians often takes place using paper forms
- Sharing of patient health information between **primary care physicians & after hours health providers is common**, but there are very **few systems to enable sharing with other providers**

- 4 sources (public, private, PPP, donor) provide eHealth funding
- **Public funding** provides more than 75% of eHealth funding

- Patients are **more likely to use the Internet** to search for health info (vs 59%), as likely to know how to use it (vs 90%), & are more trusting (vs 74%), than average patients in the EU
- **Fewer than 5%** of patients currently **access their healthcare information online**; many are not aware they are able to do so
- **HCPs are provided with eHealth education programmes** that specifically offer training in digital & data analytics

- Data across **5-6 key national datasets** is linked for **statistical analysis & research purposes**

# Use of EHRs is widespread, but sharing across healthcare providers is uncommon and linkage attempts were shut down

## Health data profile: Netherlands (2/2)



✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	✓
	Use of unique identifying number for record linkage*	-
	Use of national data to record linkage projects*	-
	Specific rules & standards on EHR interoperability	x
Quality assurance	Quality audits of EHR records	x
	Certification that requires vendors to (1) adopt standards & (2) use structure data	x
	Incentives or penalties to support quality	●
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	x
	Specific authorisation to host & process EHRs	x
	Legal requirement for encrypted data in EHRs	x
	Specific rules for archiving duration of EHRs	x
	Specific law on 2° use of data	✓
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	3/3
Patient consent	Legal rules on patient consent	x
	Rules on a patient's consent to create EHRs	x
	Rules on a patient's consent to share the EHR	✓
Access & update of EHRs	Rules on identification & access of HCPs	x
	Explicit prohibitions	✓
	Patient right to full access	✓
	Patient right to modify or erase data	✓
Data protection	Requirement for DPO (pre-GDPR)	x
	Breach notification requirement	✓
	Cyber security law	x

- Residents & non-residents who stay for longer than 4 months are given a **citizen service number** (burgerservicenummer, BSN) that is used to identify citizens for **healthcare services, government agencies & educational providers**

- Dutch law accounts for **2° uses** of data for **research purposes** as well as **statistical analysis**
- The Ministry of Health had put effort into developing a **national law** to allow the creation of a national exchange point (LSP) for **sharing EHRs**, but the **Senate voted unanimously against the law** in 2011
- Explicit consent** is required for sharing data by HCPs with 3<sup>rd</sup> parties, unless there is a **specific 'treatment relation'** with the 3<sup>rd</sup> party in case of 'push traffic' (sending data to HCP with the treatment relationship with the 3<sup>rd</sup> party, without the HCP having to take any additional action)
- Patients have the **right to erase data** inputted by another person about them into a system
- Several hospitals in the Netherlands (e.g. Medical Centre Haaglanden, the Radboud University Medical Center and University Medical Center Utrecht) have **facilitated electronic access** to medical records **for patients**
- In order to access confidential patient records, healthcare providers must obtain a **UZI card** from the Dutch Unique Healthcare Provider Identification Register, **using an AGB code** (Algemeen Gegevensbeheer Zorgverleners, the General Database for Care Providers)
  - The AGB code is used for **invoicing** between **health insurers & providers**

EHR=electronic medical record; DPO=data protection officer; HCP=healthcare professional ; \*Out of 10 types of data that can be linked

Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OEDC 'Health Data Governance'; NICTZ Website; NL Government Website; external interviews; A.T. Kearney analysis; IQVIA analysis



# EHRs spreading and unique ID numbers could allow sharing and linkage, but legal and access issues remain

## Health data profile: Poland (1/2)

✓ x=yes / no      ● ● ● = low / medium / high

Political		
eHealth national strategy	National eHealth policy or strategy	✓
	National plan or policy to implement EHRs	✓
	National plan or policy inc. 2° uses of data	✓
EHR systems	Implementation of national EHR	✓
	Primary care facilities with EHR	15%
	Specialist facilities with EHR	10%
	Hospitals with EHR	5%
Economic		
Provision of funding	Number of eHealth funding sources*	2/4
	Sum of eHealth funding amounts	100%
	Driver of eHealth funding	Public
	Public-private partnerships for eHealth	0%
Societal		
Patient trust & autonomy	Use of Internet to search for health info.	60%
	Knowledge of how to use health-related info. found online	93%
	Trust in health & medical bodies to protect data	61%
Training in eHealth	Health sciences students with pre-service training in eHealth	63%
	HCPs with in-service training in eHealth	38%
Technical		
Disease complex.	Quality of population-based cancer registries	●
	Operational national cancer plans	✓
Definition & standards	Defined minimum dataset	✓
	Structuring of data elements	●
	Rules on common terminology for EHR	✓

- Since 2014, it is **mandatory** for hospitals to use EHR but uptake is slow
  - Poland is beginning to implement a **single patient account system** that is accessed by patients over the internet & includes **lab test results & prescriptions**
  - There are plans to implement an **electronic ID** for patients & HCPs
  - The **National Centre for Health Information Systems (CSIOZ)**, established in 2009, is responsible for implemented **two major e-health platforms**, as well as developing & **setting standards for clinical terminology & interoperability**
  - **Clinical terminology standards** are also the responsibility of the **National Normalisation Committee**, in collaboration with the **European Committee for Standardisation (CEN)**
  - Some primary care physicians & HCPs in private networks of clinics & hospitals are **sharing patient medical data**, e.g. a consortium of hospitals in Lower Silesia is **sharing radiation results electronically**
- 2 sources (public, private) provide eHealth funding
  - **Public funding** provides more than 75% of eHealth funding
- Patients are **as likely to use the Internet** to search for health info (vs 59%), as likely to know how to use it (vs 90%), but are less trusting (vs 74%), than average patients in the EU
- **A unique patient identifying number (PESEL)** is assigned to **all citizens** at birth & to permanent residence holders

# EHRs spreading and unique ID numbers could allow sharing and linkage, but legal and access issues remain

## Health data profile: Poland (2/2)

✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	x
	Use of unique identifying number for record linkage*	4/10
	Use of national data to record linkage projects*	0/10
	Specific rules & standards on EHR interoperability	✓
Quality assurance	Quality audits of EHR records	x
	Certification that requires vendors to (1) adopt standards & (2) use structure data	x
	Incentives or penalties to support quality	●
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	✓
	Specific authorisation to host & process EHRs	x
	Legal requirement for encrypted data in EHRs	✓
	Specific rules for archiving duration of EHRs	x
	Specific law on 2° use of data	✓
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	3/3
Patient consent	Legal rules on patient consent	x
	Rules on a patient's consent to create EHRs	x
	Rules on a patient's consent to share the EHR	x
Access & update of EHRs	Rules on identification & access of HCPs	✓
	Explicit prohibitions	x
	Patient right to full access	✓
	Patient right to modify or erase data	x
Data protection	Requirement for DPO (pre-GDPR)	x
	Breach notification requirement	✓
	Cyber security law	x

- Data custodians **cannot share identifiable data** containing the unique PESEL number & **linking of data using it is forbidden**
- It is possible to **link data probabilistically** using other identifying information, but in practice this has **only been piloted** as a study involving linking a cancer registry to data on cancer screening
- There are **multiple specifications for a minimum dataset**, but the National Centre for Health Information Systems is **working to consolidate** this

- Polish law accounts for **2° uses** of data for **general research & specific scientific purpose**
- There are **legal issues** relating the **data access** which are yet to be resolved, despite the existence of a **new law on medical information**
- Telecommunication service providers are **required by law to report any breaches** to the **Polish Data Protection Authority**, as well as **relevant individuals**

EHR=electronic medical record; DPO=data protection officer; HCP=healthcare professional ; \*Out of 10 types of data that can be linked

Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OECD

'Health Data Governance'; External interviews; A.T. Kearney analysis; IQVIA analysis

# Use and sharing of EHRs is fragmented across regions, but efforts to create a national hub will support sharing of patient data

## Health data profile: Spain (1/2)



✓ x = yes / no      ● ● ● = low / medium / high

Political		
eHealth national strategy	National eHealth policy or strategy	x
	National plan or policy to implement EHRs	✓
	National plan or policy inc. 2° uses of data	x
EHR systems	Implementation of national EHR	✓
	Primary care facilities with EHR	90%
	Specialist facilities with EHR	25%
	Hospitals with EHR	70%
Economic		
Provision of funding	Number of eHealth funding sources*	4/4
	Sum of eHealth funding amounts	100%
	Driver of eHealth funding	Public
	Public-private partnerships for eHealth	25%
Societal		
Patient trust & autonomy	Use of Internet to search for health info.	55%
	Knowledge of how to use health-related info. found online	90%
	Trust in health & medical bodies to protect data	74%
Training in eHealth	Health sciences students with pre-service training in eHealth	25%
	HCPs with in-service training in eHealth	38%
Technical		
Disease complex.	Quality of population-based cancer registries	●
	Operational national cancer plans	✓
Definition & standards	Defined minimum dataset	✓
	Structuring of data elements	●
	Rules on common terminology for EHR	✓

- Shared EHR systems are at **different development stages**:
  - Autonomous communities develop **regional policies for their own EHR systems** but **coordination efforts** ensure that regional developments **support national plans**
  - **Barcelona** uses **registries for primary & some hospital care** & others are being developed by the regional department of health
  - **Catalunya** have a **registry to help track drug effectiveness & prices** & where they can, local registries with ad hoc protocols are set up
- In 2006, the **Ministry of Health, Social Services & Equality** through the Medical Records in the National Health System took **responsibility for EHR implementation**
  - Interoperability of systems is in **deployment at the regional level**
- There are **no national plans to extract data** from EHRs for analysis
- Spain is currently **establishing a central national node** as a hub for messaging services between HCPs in each territory
  - Territory-level nodes are **managed by healthcare authorities** & act a **concentrators of EHRs** from diverse systems (9 types of document have been identified to be included at the national level)
- Although there is a **2016 national cancer plan** in place, **regional plans** take precedence & address health data in disparate ways
- 4 sources (public, private, PPP, donor) provide eHealth funding
- **Public funding** provides more than 75% of eHealth funding
- Patients are **less likely to use the Internet** to search for health info (vs 59%), as likely to know how to use it (vs 90%), & are as trusting (vs 74%), as patients in the EU
- **HCPs are provided with eHealth education programmes** that specifically offer training in digital & data analytics



# Use and sharing of EHRs is fragmented across regions, but efforts to create a national hub will support sharing of patient data

## Health data profile: Spain (2/2)



✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	✓
	Use of unique identifying number for record linkage*	-
	Use of national data to record linkage projects*	-
	Specific rules & standards on EHR interoperability	✓
Quality assurance	Quality audits of EHR records	✓
	Certification that requires vendors to (1) adopt standards & (2) use structure data	x
	Incentives or penalties to support quality	●
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	✓
	Specific authorisation to host & process EHRs	x
	Legal requirement for encrypted data in EHRs	x
	Specific rules for archiving duration of EHRs	x
	Specific law on 2° use of data	✓
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	3/3
Patient consent	Legal rules on patient consent	✓
	Rules on a patient's consent to create EHRs	x
	Rules on a patient's consent to share the EHR	x
Access & update of EHRs	Rules on identification & access of HCPs	✓
	Explicit prohibitions	x
	Patient right to full access	✓
	Patient right to modify or erase data	x
Data protection	Requirement for DPO (pre-GDPR)	x
	Breach notification requirement	✓
	Cyber security law	x

- A minimum dataset was **established in 2010** but **incorporated 27% of all patient records** when it was launched
- 60% of patients have a **smart identity 'chipped' card**, a "DNI-e"
- Patient record sharing typically does **not extend beyond a hospital network**
- However, in groups of regions, there are initiatives underway to **enable hospitals to share minimum sets** of clinical reports including **lab reports & medical images** with other hospitals, nationally
- Data across **3-4 key national datasets** is linked for **statistical analysis & research purposes**
- Spanish legislation outlines **clinical history access** as possible for **judicial, epidemiological, public health, research or education 2° purposes**, but it must comply with the General Health legislation **data protection requirements**
- **ICT providers** of health data systems may **charge HCPs or researchers** for access to data for **2° uses**
- There are more than **20 custodians of databases** from EHR systems in Spain, involving **both regional health authorities & local custodians**
- **Strong bureaucracies & a lack of written policies** to support applicants seeking access to data **hinder wide access**
- Breach notifications must be **reported to Regulators** & the Telecommunications General Act requires telecommunication service providers to **report data breaches to subscribers or individuals whose personal data may be affected**

# Sweden has implemented a shared EHR system across all care units and linkages between patient and cancer registries exist

## Health data profile: Sweden (1/2)



✓ x = yes / no      ● ● ● = low / medium / high

Political		
eHealth national strategy	National eHealth policy or strategy	✓
	National plan or policy to implement EHRs	x
	National plan or policy inc. 2° uses of data	-
EHR systems	Implementation of national EHR	✓
	Primary care facilities with EHR	100%
	Specialist facilities with EHR	100%
	Hospitals with EHR	100%
Economic		
Provision of funding	Number of eHealth funding sources*	2/4
	Sum of eHealth funding amounts	100%
	Driver of eHealth funding	Public
	Public-private partnerships for eHealth	25%
Societal		
Patient trust & autonomy	Use of Internet to search for health info.	70%
	Knowledge of how to use health-related info. found online	94%
	Trust in health & medical bodies to protect data	88%
Training in eHealth	Health sciences students with pre-service training in eHealth	75%
	HCPs with in-service training in eHealth	75%
Technical		
Disease complex.	Quality of population-based cancer registries	●
	Operational national cancer plans	✓
Definition & standards	Defined minimum dataset	✓
	Structuring of data elements	●
	Rules on common terminology for EHR	✓

- A shared EHR system was **fully implemented in 2012**
  - The Swedish e-Health strategy coordinates **national EHR implementation** but country & municipal councils are **responsible for their own implementations**; governance was started in 2000
    - The National Board of Health & Welfare sets the **clinical terminology standards**, & the Swedish Association of Local Authorities & Regions sets **national standards for electronic messaging**
  - All hospitals, primary & specialist care centres use EHRs & **data is shared** between different care units, including those within the same country council / health authority
  - **Contracted individual care givers also share patient data** with the country's national system
  - There is a **comprehensive programme of data linkages** to facilitate healthcare quality monitoring, including linkage of cancer & patient registries
- 
- 2 sources (public, PPP) provide eHealth funding
  - **Public funding** provides more than 75% of eHealth funding
- 
- Patients are **more likely to use the Internet** to search for health info (vs 59%) or know how to use it (vs 90%), & are more trusting (vs 74%), than average patients in the EU
- 
- The national EHR system is a **shared national patient summary record**; the **Personnummer** (personal identity number) is used for all office purposes (tax, social welfare, healthcare, education etc)
  - **Smart cards** are available for HCPs but not for patients
  - **Minimum dataset established in 2010** but covers **10% of patients**

# Sweden has implemented a shared EHR system across all care units and linkages between patient and cancer registries exist

## Health data profile: Sweden (2/2)



✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	✓
	Use of unique identifying number for record linkage*	7/10
	Use of national data to record linkage projects*	7/10
	Specific rules & standards on EHR interoperability	✓
Quality assurance	Quality audits of EHR records	x
	Certification that requires vendors to (1) adopt standards & (2) use structure data	✓
	Incentives or penalties to support quality	●
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	✓
	Specific authorisation to host & process EHRs	x
	Legal requirement for encrypted data in EHRs	x
	Specific rules for archiving duration of EHRs	x
	Specific law on 2° use of data	✓
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	3/3
Patient consent	Legal rules on patient consent	✓
	Rules on a patient's consent to create EHRs	✓
	Rules on a patient's consent to share the EHR	✓
Access & update of EHRs	Rules on identification & access of HCPs	✓
	Explicit prohibitions	x
	Patient right to full access	x
	Patient right to modify or erase data	x
Data protection	Requirement for DPO (pre-GDPR)	x
	Breach notification requirement	✓
	Cyber security law	x

- **Cancer registries are linked** to the patient register & linkage is generally **conducted in some country councils** (e.g. Skane & West Regions); 7 national databases use the Personnummer
- The National Board of Health & Welfare conducts **linkages using the identification number**, but analysts in government & external researchers are **only allowed access to de-identified data**
- Data is de-identified by the Health & Welfare Board by **removing national identity numbers, names, addresses & date of births**; files are provided to analysts & researchers with a **study number** and **some personal information** such as sex, age & community
- Data across **7+ key national datasets** is linked for **statistical analysis & research purposes**
- There are **>20 custodians of databases** created from EHR systems
- **2° data use** is permitted, to **develop & safeguard the quality of health care**, assist **planning, evaluation & follow-up & statistics**
- If a patient wishes to have their data removed from a registry, they must **appeal to national health authorities**; patients **do not have direct control** over the deletion & modification of their data
- Patients are **asked for consent** by health centres to use personal data for other uses; previously patients were informed in retrospect
- The Swedish **1177 platform allows patients to set clear consent rules** for the personal health data
- In case of a data breach, The Electronic Communications Act requires electronic service providers to **notify the Post and Telecom Authority (PTS)** of **“privacy incidents”** & **individuals** if the incident is expected to have a **negative impact**
- Access to individual databases is **agreed on a case-by-case basis**; access to multiple & linkage between them is agreed with the **Swedish Association of Local Authorities & Regions (SALAR)**

EHR=electronic medical record; DPO=data protection officer; HCP=healthcare professional ; \*Out of 10 types of data that can be linked

Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; OECD

'Health Data Governance'; External interviews; A.T. Kearney analysis; IQVIA analysis



# Data sharing is limited across health care centres due to regional disparities, but encrypted identifiers are enabling linkage

## Health data profile: Switzerland (1/2)



✓ x = yes / no      ● ● ● = low / medium / high

Political		
eHealth national strategy	National eHealth policy or strategy	✓
	National plan or policy to implement EHRs	✓
	National plan or policy inc. 2° uses of data	x
EHR systems	Implementation of national EHR	✓
	Primary care facilities with EHR	20%
	Specialist facilities with EHR	-
	Hospitals with EHR	90%
Economic		
Provision of funding	Number of eHealth funding sources*	3/4
	Sum of eHealth funding amounts	75%
	Driver of eHealth funding	Private / Public
	Public-private partnerships for eHealth	25%
Societal		
Patient trust & autonomy	Use of Internet to search for health info.	-
	Knowledge of how to use health-related info. found online	-
	Trust in health & medical bodies to protect data	-
Training in eHealth	Health sciences students with pre-service training in eHealth	25%
	HCPs with in-service training in eHealth	75%
Technical		
Disease complex.	Quality of population-based cancer registries	●
	Operational national cancer plans	✓
Definition & standards	Defined minimum dataset	✓
	Structuring of data elements	●
	Rules on common terminology for EHR	x

- **eHealth Suisse** is responsible for **coordinating the work of four working groups** on standards & architecture, pilots & implementation, & education in EHRs – this was established in 2008
- **Encrypted identifiers**, created by Swiss cantons via algorithms, are provided to the Federal Statistical Office (FSO) to enable **linkages**
- The FSO is seeking the opinion of the Swiss national Office of Data Protection to determine the **legal authority to process data** using the **Social Security Number**
- In 2015 the Swiss Federal Parliament passed a law that makes **adoption of interoperable EHRs** in hospitals & nursing homes mandatory, & they must be **compatible with national standards**; it came into effect in **April 2017**
- Differing regional needs in Switzerland mean that **data sharing capabilities** in hospitals are dispersed

- 3 sources (public, private, PPP) provide eHealth funding
- **Public funding** provides less than 25% of eHealth funding; **private & public funding** are the main drivers
- Until 10-15 years ago, funding for data sources was **mostly local & ad hoc** which lead to **inefficiencies**
- More systematic **national & regional funding** was spurred on by government recognition of the importance of **using RWD to evaluate quality of care**

- Students have **less eHealth training**, & **HCPs more**, than other EU countries
- **HCPs are provided with eHealth education programmes** that specifically offer training in digital & data analytics

# Data sharing is limited across health care centres due to regional disparities; but encrypted identifiers are enabling linkage

## Health data profile: Switzerland (2/2)



✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	✓
	Use of unique identifying number for record linkage*	3/10
	Use of national data to record linkage projects*	5/10
	Specific rules & standards on EHR interoperability	-
Quality assurance	Quality audits of HER records	✓
	Certification that requires vendors to (1) adopt standards & (2) use structure data	x
	Incentives or penalties to support quality	●
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	-
	Specific authorisation to host & process EHRs	-
	Legal requirement for encrypted data in EHRs	-
	Specific rules for archiving duration of EHRs	-
	Specific law on 2° use of data	-
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	-
Patient consent	Legal rules on patient consent	-
	Rules on a patient's consent to create EHRs	-
	Rules on a patient's consent to share the EHR	-
Access & update of EHRs	Rules on identification & access of HCPs	-
	Explicit prohibitions	-
	Patient right to full access	-
	Patient right to modify or erase data	-
Data protection	Requirement for DPO (pre-GDPR)	x
	Breach notification requirement	x
	Cyber security law	x

- Switzerland specified a **minimum dataset in 2009**, such that **90% of all patients** have an EHR containing it
- National EHR adoption laws that came into force in April 2017 required both **patients & healthcare** providers to have a **unique electronic ID**, to enable EHR sharing & linkage across databases
- **Data linkage** is conducted with **5-6 national databases** using data which has the unique electronic patient ID
- Data across **1-2 key national datasets** is linked for **statistical analysis & research purposes**

- When data files are provided to an external researcher, a contract with the FSO binds them to **protect the data following given guidelines**; if these guidelines are infringed, **data must be destroyed**
- **No audit of external researchers** takes place, but publications & case studies are **tracked for adherence** to the agreed-upon purpose of the study
- A new national law set **certification requirements** for communities of health care providers to follow, in order to **share records with others**; the law aims to ensure **regional systems will be interoperable**

EHR=electronic medical record; DPO=data protection officer; HCP=healthcare professional ; \*Out of 10 types of data that can be linked

Source: Cancer Atlas; WHO. 'Global eHealth survey' (2015); European Commission. 'Overview of national laws on EHR' (2013); OECD. 'Strengthening Health Info Infrastructure' (2015); Eurobarometer surveys on 'Digital health literacy' and 'Data protection'; Taylor Wessing. 'Global data protection guide', access Mar 2018; University of Applied Sciences and Arts of Southern Switzerland "eHealth in Switzerland" (2015); external interviews; A.T. Kearney analysis; IQVIA

# Unified national policies exist for both EHR implementation and oncology data collection; legal barriers remain prevalent in the UK

## Health data profile: United Kingdom (1/2)



✓ x = yes / no      ● ● ● = low / medium / high

Political			
eHealth national strategy	National eHealth policy or strategy	✓	
	National plan or policy to implement EHRs	✓	
	National plan or policy inc. 2° uses of data	✓	
EHR systems	Implementation of national EHR	✓	
	Primary care facilities with EHR	100%	
	Specialist facilities with EHR	20%	
Hospitals with EHR	Hospitals with EHR	100%	
	Economic		
	Provision of funding	Number of eHealth funding sources*	2/4
		Sum of eHealth funding amounts	100%
Driver of eHealth funding		Public	
Public-private partnerships for eHealth		25%	
Societal			
Patient trust & autonomy	Use of Internet to search for health info.	60%	
	Knowledge of how to use health-related info. found online	95%	
	Trust in health & medical bodies to protect data	81%	
Training in eHealth	Health sciences students with pre-service training in eHealth	38%	
	HCPs with in-service training in eHealth	63%	
Technical			
Disease complex.	Quality of population-based cancer registries	●	
	Operational national cancer plans	✓	
Definition & standards	Defined minimum dataset	✓	
	Structuring of data elements	●	
	Rules on common terminology for EHR	✓	

- **NHS identifying number** is used to provide health services, but is **not linked** to other social security systems
- The **NHS 5-year Cancer Strategy**, laid down in 2016, includes top-line plans **for the collection & use of data for oncology**
- The **Cancer Drugs Fund**, established in 2011 to fund new oncology drugs, now collects observational data on patient outcomes for all drugs funded by the scheme
- **Connecting for Health**, established in 2005, is responsible for the **EHR infrastructure in NHS England**, including managing terminology & interoperability standards
- The **Information Standards Board** appraises & approves **standards for clinical information**; its members including clinical, managerial & technical experts
- In Scotland, there is **no body responsible for EHR infrastructure**; it is managed by the **Scottish Government's eHealth** division that also sets terminology & interoperability standards
- 2 sources (public, PPP) provide eHealth funding
- **Public funding** provides more than 75% of funding for eHealth
- Patients are **as likely to use the Internet** to search for health info (vs 59%), or know how to use it (vs 90%), & are more trusting (vs 74%), than average patients in the EU
- A **minimum dataset** was established in 2006 in England; **25% of patients** now have this summary record
- Scotland has specified **14 sets of information via a clinical portal**

# Unified national policies exist for both EHR implementation and oncology data collection; legal barriers remain prevalent in the UK

## Health data profile: United Kingdom (2/2)

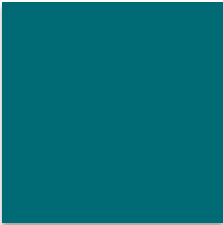
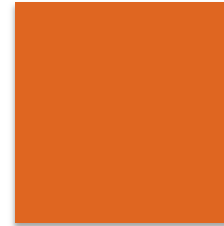
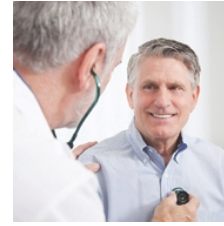
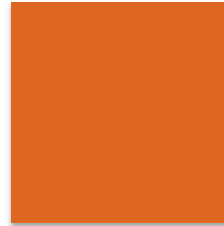
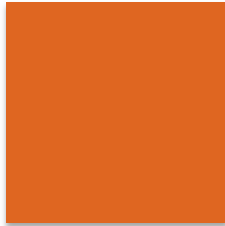


✓ x = yes / no      ● ● ● = low / medium / high

Technical (cont.)		
Interoperability & linkage	Electronic sharing of information about patients	✓
	Use of unique identifying number for record linkage*	10/10
	Use of national data to record linkage projects*	9/10
	Specific rules & standards on EHR interoperability	x
Quality assurance	Quality audits of HER records	✓
	Certification that requires vendors to (1) adopt standards & (2) use structure data	✓
	Incentives or penalties to support quality	●
Legal		
Hosting & processing	Specific rules on hosting & processing of EHRs	✓
	Specific authorisation to host & process EHRs	✓
	Legal requirement for encrypted data in EHRs	x
	Specific rules for archiving duration of EHRs	x
	Specific law on 2° use of data	✓
	Use of 3 <sup>rd</sup> parties to (1) create, (2) de-identify or (3) approve data requests for access	1/3
Patient consent	Legal rules on patient consent	✓
	Rules on a patient's consent to create EHRs	✓
	Rules on a patient's consent to share the EHR	✓
Access & update of EHRs	Rules on identification & access of HCPs	✓
	Explicit prohibitions	x
	Patient right to full access	x
	Patient right to modify or erase data	x
Data protection	Requirement for DPO (pre-GDPR)	x
	Breach notification requirement	✓
	Cyber security law	x

- Across the UK, cancer incidence data is in **various stages of linkage**:
  - In **England**, it is linked to mortality, treatment & primary care data
  - In **Scotland**, it is linked permanently to in-patient data, mental hospital in-patient data & mortality data
  - In **Wales**, the cancer registry is only linked to mortality data
- The process for dissemination of information outside the NHS (in both England & Scotland) involves researchers accessing a file where **personal identifiers have been removed**, & the Unique NHS number has been replaced with a **study number**
- Data across **7+ key national datasets** is linked for **statistical analysis & research purposes**
- There are more than **20 organisations** in the custody of databases developed from EHRs; all data custodians must **register their collections with the UK Information Commissioner**, who is responsible for **overseeing adherence to the Data Protection Act**
- UK law accounts for **2° data uses** that cover **research & scientific purposes, epidemiology & statistical analysis**
- Data linkage can take place **without prior consent**; data custodians must **inform patients where their data is being used**, & is mostly conducted by national authorities, however UK law does not rule out **non-governmental organisations** getting approval for this process
- If a data breach occurs, The Privacy and Electronic Communications Act 2011 requires service providers to **notify the ICO** & in some cases the **subscriber of a data breach**; if the breach is likely to **adversely affect an individual's privacy, the data subject must also be notified**





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