Letter of 9 April 2019 from the Minister for Medical Care and Sport, Bruno Bruins, to the House of Representatives on electronic data exchange in the healthcare sector (second letter on this topic)

Good, timely exchange of information between healthcare providers and with patients is essential for good quality care. All too often, care professionals do not have the information they need. They also spend too much time faxing information or copying data onto DVDs. Patients have to recite their case history over and over again, while they're thinking 'surely you know that, doctor'. That is why digital must become the new normal and why I will take concrete steps towards making electronic data exchange a statutory obligation, as set out in my first letter on accelerating electronic data exchange, sent to the House on 20 December 2018.[1]

I begin this second letter about electronic data exchange with a brief summary of the previous letter, before describing the outlines of the forthcoming statutory obligation and my proposed roadmap identifying care processes that have priority in digitalisation, thus also responding to the motion[2] submitted to the House by Rens Raemakers, Joba van den Berg and Arno Rutte to keep the House informed of the direction I am taking in these matters. Finally, in annex 1 I respond to a number of issues raised at the parliamentary committee meeting of 30 January 2019 and to various motions subsequently passed by the House.

Background

In my letter of 20 December 2018 I wrote that the obstacles to electronic data exchange must be tackled in the interests of patients, who are entitled to good-quality care – for which good information provision and data exchange are vital. I described the current shortcomings in electronic data exchange and my intention to introduce a statutory obligation on electronic data exchange and to develop a digitalisation roadmap.

Because of inadequate electronic data exchange in the healthcare sector, avoidable mistakes are made, patients have to recite their case history over and over again, care providers repeatedly have to enter the same data, taking up patients' time, and tests and examinations are unnecessarily repeated. Tackling these problems is not simple. The different professional groups all have their own language and this must be harmonised in a whole range of data exchanges. For instance, the acronym OAC (*orale anticoagulantia*, i.e.

[1] Parliamentary Papers 27 529, no. 166.
[2] Parliamentary Papers 35 000 XVI, no. 46.

oral anticoagulants) is sometimes misinterpreted as *orale anticonceptie* (oral contraception), which is a very different thing. Because there are so many professional groups involved, and a vast range of specialised terms, achieving uniformity of language is problematic. There are also many different technical standards and some regions do not yet have their own infrastructure for electronic data exchange or the requisite facilities (such as a digital address book). In short, there are failings in terminology and technology that must be resolved if electronic data exchange is to be improved.

Fortunately, there has been a lot of progress and major investment in digitalisation in healthcare in recent years. Under the Public Health Act, municipal child health services have been required to work digitally since 2010, with financing delegated to lower tiers of government. Electronic data exchange has a prominent place in the framework agreements with the healthcare sector, as well as in programmes to improve elderly care at home and in nursing homes, and in the report of the taskforce on 'care in the right place'.

Between 2017 and 2022 more than €400 million will be made available for the VIPP[3] schemes aimed at accelerating information exchange between patients and care professionals in mental healthcare, hospitals and independent treatment centres. This year new schemes will be introduced for perinatal care, GPs, independent mental healthcare practitioners and long-term care, and there will be a follow-up programme for hospitals and independent treatment centres. Patients who wish to can also access their own data in their personal health environment (PHE), which complies with the MedMij rules on digital exchange of health data. I recently announced that in the years to come every person in the Netherlands will be able to use a PHE free of charge.

Care providers are busy improving data exchange with patients and increasing patients' use of these data. This is only possible if care professionals record and share their data electronically, which is also why I want to accelerate electronic data exchange between care providers. My ambition is to achieve complete digitalisation of healthcare data sharing in the Netherlands in the near future – through stricter government control, faster progress and a statutory obligation.

Statutory obligation

I am preparing a statutory obligation for care providers and institutions to keep digital patient records and share data electronically, in accordance with uniform standards concerning

[3] Scheme to accelerate the exchange of information between professionals and patients.

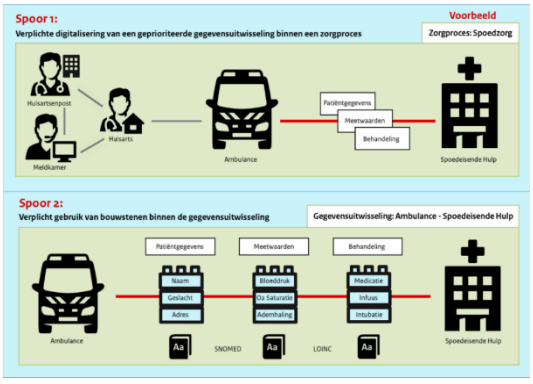
terminology and technology. The statutory obligation will be introduced for one information-sharing process at a time. The roadmap will set out which processes have priority in digitalisation for the purposes of electronic data exchange.

The statutory obligation will have two tracks. The first concerns the question of which care processes are to be digitalised. The second focuses on the question of how digital data exchange should take place.

Track one: identifying processes for digitalisation

Emergency care is one example of a care process that has priority in mandatory digitalisation. Emergency care involves more than 20 different information exchanges ('handover'), such as between the emergency call centre and the ambulance. The information that must be shared will be laid down by care professionals in field standards that provide uniformity of terminology and technology. These standards will be made mandatory.

Continuing this example, emergency care also involves handovers between the out-of-hours GP service and the emergency call centre, between the out-of-hours GP service and the accident and emergency unit (A&E), and between the ambulance and A&E. When a patient is transferred from the ambulance to A&E, different types of information must be shared, including patient identifiers, vital signs or test results and what treatments have been initiated. These information categories are made up of various components, such as patient's blood pressure. This component, which is part of vital signs, includes all the information relating to blood pressure, such as systolic and diastolic pressure and the patient's posture when the measurement was taken, presented in accordance with the language standard. The figure below depicts the two tracks in mandatory data exchange.



Track 1: Example

mandatory digitalisation of a prioritised information exchange in a care process

Care process: emergency care

Out-of-hours GP			Patient identifiers	
	GP	Ambulance	Test results/vital signs	A&E
Emergency call centre			Treatment	

Track 2:

Mandatory use of components during information exchange

Handover: ambulance to A&E

	Patient identifiers	Test results	Treatment	
	-Name	-Blood pressure	-Medication	
Ambulance	-Sex	-O_2 saturation	-IV insertion	A&E
	-Address	-Respiratory rate	-Intubation	
		SNOMED	LOINC	

A component can be shared in numerous information exchanges. In other words, the same component can feature in several different handovers. Blood pressure, for instance, is shared when a patient is transferred from the ambulance to A&E as well as at handover to the home care organisation on the patient's discharge. The information shared at any handover always consists of multiple components.

The first track of the statutory obligation therefore consists of designating which handovers must be subject to mandatory electronic data exchange and which components are to be included in each of these handovers.

Track two: mandatory components and mandatory terminologies

Information components like blood pressure are shared during several different handovers and it is important that this information is always presented in the same way. The second track of the statutory obligation thus involves designating mandatory components of electronic data exchange and prescribing which terminologies must be used to communicate that information. SNOMED CT and LOINC are examples of international terminologies. SNOMED CT, for instance, has fixed terms to describe the patient's position when a blood pressure measurement is performed (e.g. recumbent, sitting, orthostatic body position), ensuring that the sender and receiver of the information understand each other. As these

terminologies are used internationally I will – as I informed the House previously[4] – work at international level to promote and generate support for our standardised system of data exchange between care professionals and with patients. International cooperation can thus contribute towards the digitalisation of healthcare in the Netherlands, enable us to make maximum use of European funds, and help Dutch suppliers tap into a broader international market.

The introduction of the statutory obligation means the government's role in the development and management of the information components will also change. The exact form this role will take will become apparent in the legislative process.

The healthcare IT infrastructure must be such that data can indeed be successfully exchanged, for instance between an ambulance crew and A&E staff. So I want the requirements concerning terminology and technology also to instantly apply to the health systems and infrastructures developed by commercial parties. This avoids individual care providers having to set this as a separate procurement requirement. I am considering introducing mandatory certification for health information technologies (HIT) so that suppliers know exactly what requirements they need to meet. The associated standards will be drawn up in consultation with the industry. An initial step has already been taken in the form of a manifesto sent by the Confederation of Netherlands Industry and Employers (VNO-NCW) and various parties in the healthcare sector to the Dutch federation of patients' associations and me, in which they pledge to streamline and improve the security of data exchange in healthcare.[5] I am supporting the signatories' efforts in getting all HIT suppliers on board and in transforming the agreements into concrete proposals, by suppliers, to accelerate digitalisation in healthcare.

Finally, the new legislation will include provisions on monitoring and enforcement. To this end, I will also consult the Healthcare Institute of the Netherlands, the Health and Youth Care Inspectorate and the Dutch Healthcare Authority when drafting the bill.

I intend to present a draft bill for consultation this year, which can then be submitted to the House around summer 2020, with a view to publication on 1 January 2021. From the moment the bill enters into force, the number of processes for which electronic data

[4] Parliamentary Papers 27 529, no. 160.
[5] The manifesto is entitled 'Samen Vooruit'. For more information (in Dutch) see: https://www.vno-ncw.nl/nieuws/nooit-meer-faxen-de-zorg.

exchange will be mandatory will increase gradually, ultimately resulting in a comprehensive, nationwide system that covers the entire healthcare sector.

The digitalisation roadmap: which exchanges of data must be digitalised first?
In track one we will designate in phases which data exchange processes must take place electronically. In recent months, parties in the sector have given their – partly overlapping – views on this during consultation sessions and in writing. Building on the list drawn up with Nictiz (the Netherlands' centre of expertise on e-health), I now have a list of 13 processes that qualify for accelerated digitalisation and will be included in the first edition of the roadmap. This list is based on the following three criteria:

- Added value
  The primary factor is the added value of digitalisation for healthcare professionals and patients: the extent to which it serves the interests of patient health. Digitalisation must for instance reduce the risk of avoidable mistakes, e.g. because information on medication and allergies is available to A&E staff. Another important factor is volume – the number of patients who benefit directly from electronic data exchange. Efficiency is also important: digitalisation must reduce the administrative burden of healthcare organisations and professionals. Finally, the improvements must also be perceived by patients. This is why the digitalised data must comply with the MedMij standards, so that the information shared between healthcare providers is also accessible to patients through their personal health environment.

- Feasible
  Digitalisation also needs to be practicable. Among other things, professionals must have made agreements on what information (components) is shared in a process, and data exchange must be technically possible through a national network of linked-up health information infrastructures. Finally, it must be clear what actions are to be carried out by what parties, what risks are associated with each activity, to what extent existing programmes (including VIPP) have paved the way for the projected digitalisation and what the quantitative and qualitative results of digital data exchange will be (the business case). The digitalisation of care processes will be carried out parallel to existing programmes like VIPP and will be financed in line with care institutions' existing rates for regular operational management. In this connection I am counting on HIT suppliers to contribute to the development of the necessary standards, infrastructures and facilities and to their implementation.

- Support

  Finally, support, commitment and determination on the part of all stakeholders in the field is crucial if this plan is to succeed. A statutory obligation, no matter how important in achieving digitalisation, is after all only the final piece of a complex operation carried out by healthcare professionals, organisations, HIT suppliers and others.

Proposed roadmap

The statutory obligation to keep digital patient records and exchange data digitally will be introduced in phases. Based on an initial general assessment,[6] in particular of feasibility, the following 13 processes are included in the proposed roadmap for the digitalisation of priority processes:

- Ambulance handover to A&E
- Medication overview and electronic prescribing
- Supplying and administering medication
- Sharing of Patient Summary (BgZ) data between hospitals
- Discharge summary from hospital to care institution or homecare organisation
- Integrated care of diabetes patients
- Clinical handover of Patient Summary in mental healthcare
- Handover in acute obstetric situations between midwives and gynaecologists
- Diagnostic imaging exchange between hospitals
- Pathology image exchange (PIE)
- Multidisciplinary oncological consultation
- Triage referral – data exchange from out-of-hours GP to emergency call centre and A&E
- Electronic data exchange between perinatal care and municipal child health services (baby and toddler clinic)

General plan

The first data exchange processes to fall under the statutory obligation on digitalisation will be taken from the list above. Over the next few months I will be working with parties in the field to flesh out the details of this list. I want to ensure that 13 exchange processes really do result in electronic data exchange. To that end the final list will only include processes where

[6] The first analyses of each information-sharing process were published (in Dutch) at the beginning of March 2019 on https://www.informatieberaadzorg.nl/over-het-informatieberaad/publicaties/publicaties/2019/3/7/concept-roadmap-gegevensuitwisseling---eerste-editie.

digitalisation is demonstrably feasible. This relates to uniformity of terminology (do the healthcare professionals involved agree on the field standards, on what information is being shared and what terms are used, have all the components been identified) and uniformity of technology (are technical standards available and can information actually be shared). I plan to provide the House with the final list before this summer, also specifying exactly what needs to be done in each case to make exchange possible.

With regard to track one of the legislation, I intend to designate a number of processes for which digital data exchange will be mandatory concurrently with publication of the act. This will ensure that professionals and patients perceive the act's impact right away. Looking at the proposed roadmap, I believe ambulance handover and electronic prescribing, for instance, could feasibly be digitalised within a reasonable timeframe. With regard to track two of the legislation, I also want to ensure that an initial list of mandatory components, using the appropriate terminology and technical standards, is published concurrently with the act. This will launch the mandatory electronic exchange of data in healthcare. As more processes are fully digitalised, more standardised components will become available and more infrastructures will be put in place to link up care providers. This will speed up and simplify digitalisation of subsequent processes.

New editions of the roadmap

I would have preferred to carry out this operation with the sector in one fell swoop. However, electronic data exchange can only be achieved in phases, based on concrete priorities. The roadmap will therefore have several editions. I will start by steering the digitalisation of processes included in the first edition. As soon as data exchange is up and running for these processes, the next set will be added to the roadmap. This will result in a multiyear plan. I do however expect the care sector to also start preparing for digitalising processes that have not yet been made mandatory.

Consent for data exchange

The phased approach to digitalisation of information sharing will result in all data always being exchanged electronically. Sometimes, but not in all cases, a patient's consent will be required.

In principle, processing of medical data is prohibited under the GDPR

In principle, the processing of medical data is prohibited under the General Data Protection Regulation (GDPR), but there are exceptions, for instance when a patient has given consent or when this is essential for the patient's treatment (treatment contract). This is laid down in the Medical Treatment Contracts Act (WGBO). Among other things the WGBO provides that patients must give consent before data in their medical records can be shared with third parties. However the WGBO also provides for various exceptions to this rule. Explicit consent is not required for providing vital information to someone who is directly involved in the treatment relationship or to the care provider's locum.

In my meeting of 3 April 2019 with the parliamentary committee on emergency care/ambulance care I undertook to provide clarity on the issue of consent for emergency care (i.e. in situations where patients have not given prior consent for the sharing of their data). The legal basis for processing personal data in a situation where the individual concerned is incapable of giving their consent is formed by the treatment contract pursuant to the WGBO and the data subject's vital interest as referred to in the GDPR and in section 22, paragraph 2 (b) of the General Data Protection Regulation (Implementation) Act. An example of an individual's vital interest being at stake would for example be an acute threat to their life or health. This provision must be interpreted restrictively: data should be shared without consent only when absolutely necessary and for a limited period of time. Consent should be requested as soon as possible.

So, while consent is not always necessary, the Processing of Personal Data in Healthcare (Supplementary Provisions) Act (incorporating the Electronic Processing of Data (Patient Rights) Act) (WABVPZ) does sometimes stand in the way of electronic data exchange. That is because the Act stipulates that patients must give consent separately for the sharing of data with other care providers by electronic means. If someone has not given that consent, their medical data can never be shared electronically, not even if the WGBO provides that the data can be shared. To give a concrete example, if a patient has not given their GP consent to electronically share information on their allergies, this information will not be available at all electronically – not even in a life-threatening situation.

The consequence of this for daily medical practice is that care professionals have to request consent for electronic exchange of data from medical records more often than for sharing information on paper. I regard this as undesirable: effectively, disposing of fax machines and

introducing electronic data exchange results in less rather than more information being made available. I will therefore submit a proposal to the House to amend the WABVPZ on this point. I will also consider whether the definition of a ‘system of information exchange’ adequately covers the latest technologies, as electronic medical record systems currently support direct data exchange.

Infrastructures necessary for data exchange

If data is to be exchanged by electronic means, there must be an infrastructure that is capable of actually transmitting the information, and that connects all care providers in all care domains. Currently there are several dozen infrastructures that support various types of data exchange. The fact that there are so many is due to the scale and diversity of the healthcare sector, the existence of multiple regional collaborative frameworks and the enormous variety in the types of information collected. This means the Dutch healthcare sector will never have a single infrastructure for data exchange. The main thing is that the various infrastructures comply with the agreements made so that all care providers, regardless of which infrastructure they use, are linked up with each other and that the requisite facilities, such as a digital address book, are available to them all.

To achieve this I am considering a certification system for infrastructures. I will provide more information on this in the course of the legislative process. A certification system would guarantee freedom of choice while ensuring that key requirements are met. My decision not to make a particular data exchange infrastructure mandatory is also in line with the motion submitted to the House by Femke Van Kooten-Arissen and Maarten Hijink (2018/19 session, 29 515, no. 174). More information about my policy on infrastructures can be found in annex 2.

A more coherent approach

In my first letter on accelerating electronic data exchange in healthcare I wrote about using existing programmes so that, jointly with the sector, I can achieve greater coherence and progress of both existing and new programmes. The roadmap will set the direction I intend to take. The first steps have since been taken, jointly with the sector. To give an example: sharing information about medication is a key element in the sector-wide approach to improve medication safety. I will shortly invite all the parties that play a role in the medicines process to join the Alliance on Medication Safety, through which I aim to strengthen the coherence between the many initiatives, programmes and projects on this issue taking place across the sector. The sector-wide exchange of information between care providers and with patients on medication, lab test results and data on drug intolerances, contraindications and

allergies is crucial to this process. The information shared must moreover comply with the revised guidelines on medication transfer and the information standards (agreements on terminology and technology).

The proposed roadmap mentioned in this letter has been drawn up with the sector and affirmed by the consultative committee on healthcare data exchange (*Informatieberaad Zorg*). I attended a number of the committee's meetings and noted that all the participants committed to the agreements. I am confident that they will not delay in implementing them jointly with the sectors they represent. At one of these committee meetings I affirmed that political intervention will be possible if the participants are unable to reach agreement on the terminological and technical requirements, either among themselves or with suppliers.

Practical feasibility

Ultimately, it is doctors, nurses and other care professionals whose work electronic data exchange will most impact. I am acutely aware of the importance of practical feasibility and regard digitalisation as a means of further improving the quality of care. I aim for a system that is feasible in practice and makes a noticeable difference to care professionals and patients while reducing rather than adding to their administrative burden. I fully understand the concerns of the Dutch Federation of Medical Specialists (*Federatie Medisch Specialisten*) that these points be given due attention[7] because the way in which agreements on terminology and technology are implemented in health information systems impacts on both quality of care and administrative burden.[8] The programme plan that I aim to present to the House before this summer will therefore specifically address managing for practical feasibility, for instance by providing transparency on the effects of systems' user-friendliness (or lack thereof) on quality of care, as reported by care professionals.

Concluding remarks

In this letter I have outlined the step-by-step introduction of a statutory obligation on digitalisation in the healthcare sector. A draft version of the first edition of the roadmap for electronic data exchange will be elaborated and tested in the months to come.

Before the summer I will send the House another letter on electronic data exchange in the healthcare sector, which will provide further information about the final roadmap, legislative

[7] See https://www.demedischspecialist.nl/laat-dokters-dokteren.
[8] See, for instance, https://jamanetwork.com/journals/jama/fullarticle/2676098 en Zie https://jamanetwork.com/journals/jama/fullarticle/2724003.

progress and the programme-based approach by which I intend to support the sector's transition to digitalisation in the years ahead.