Main features of the DCRA

Background information
Start registrations: 2009
Number of patients included: 100.000
Number of hospitals participating: 78

The initiator: the professional organisation of surgeons
All surgeons in the Netherlands are united in a professional organisation, the Association of Surgeons in the Netherlands (ASN). The ASN serves as a central protector of common interests of surgeons. Membership of the ASN is compulsory to all surgeons in theNetherlands. One of its main objectives is to assure that every surgical patient in the Netherlands receives high quality care. Furthermore, ASN continuously attempts to improve the quality of surgical care. TheASN uses different instruments to accomplish this, for example the development of evidence-based guidelines, surgical training programs and accreditation of surgeons in their surgical specialty. The initiation of clinical audits was necessary to facilitate the uniform measurement of quality of care and enhance the Association's quality improvement efforts.

Dataset: involvement of all experts in the field
The ASN formed a scientific committee of mandated clinical experts in colorectal cancer care (surgeons, oncologists, pathologists, epidemiologists) to initiate the first clinical audit. The scientific committee defined performance indicators and outcome measures, based on preexisting evidence based guidelines, to highlight potentialquality concerns, identify areas that need further investigation, and track changes over time. The committee defined a dataset using a Delphi method. The dataset generally covers three aspects: case-mix variables (e.g. age, gender, co morbidity) necessary for hospital comparison; process variables (e.g. wait times and number of patients discussed in a multidisciplinary team); and outcomes of care (e.g. morbidity and mortality).

Online data is self-registered in a secured web form
Each participating hospital appoints a surgeon responsible for (supervising) the data registration. The majority of the colorectal surgeons record the data themselves. The DCRA uses a generic internet based program to enable data entry in a secured web environment. Depending on the complexity of the patient and perioperative course, a number of 56-179 variables have to be completed; regis- tration time is approximately 20-30 min per patient. Data-entry can be entered either throughout patient's management or at the end of each admission. Data can be updated when necessary; for example when follow-up data is available. A third trusted party anonymises data regarding patient identification directly after data entry. Definitions and helping texts are appointed to each variable in the dataset and are available during data entry. These guarantee that registration is performed uniformly. Also, frequently asked questions (FAQs) are available on the website and a front office can be contacted by data regis- trants for questions on both technical and content issues.

Internal and external data verification
Data validity is achieved and verified in various ways. The surgeon receives direct feedback on erroneous, missing or improbable data items during data entry through quality control tools that are built in the program. Hospitals receive feedback information on the number of patients and completeness of the data to encourage the participants to correct them when needed.
Data are annually compared with an external data registration, the National Cancer Registry (NCR), on completeness and accuracy. The NCR registers all newly diagnosed malignancies in the Netherlands. Information on patient characteristics (e.g. age, gender) tumour characteristics (TNM stage, localisation, histology) treatment (surgical procedure, chemo and/or radiation therapy, laparoscopy, ur- gency of procedure) hospital of diagnosis, hospital of treat- ment and outcomes

(30-day mortality, anastomotic leakage, CRM, lymph nodes), are collected from the medical records by specially trained registrars 9 months after diagnosis. The NCR has an automatic linkage to many important and solid databases, among which the Municipal Administration (GBA), which allow the full enrolment of patients eligible for registration and notification for postoperative mortality. Quality of the NCR data is high; completeness is estimated to be at least 95%.The registration of the NCR is linked to the Municipal Administration, which by law receives notification on all patients that decease in the Netherlands.

Online feedback is provided on a weekly basis
Information regarding volume, performance indicators and outcomes of care are presented online to individual hospitals. Each participating hospital has access to its own secured website. Data are weekly updated. Results of the hospital are presented in relation to the national average and in relation to results of other anonymised hospitals.

Outcomes are adjusted for differences in case-mix
When comparing hospital outcomes differences in case-mix must be taken into account. Therefore, a set of relevant case-mix variables specific for each outcome measure is embedded in the database. A standardised co morbidity module was developed using the Delphi method with incorporation of the Charlson Co morbidity Index. Case-mix adjusted hospital outcomes are presented in funnel plots using 95% confidence limits that vary in relation to the hospital volume.

Results and targets for quality improvement are presented in an annual report
An extensive national report presenting the results of the audit is published annually. This report focuses on various themes for improvements in the scope of recent literature. The results are presented in a yearly conference accessible to clinicians, patients, patient advocates, health insurers and policy makers, politicians. The conference functions as a platform for all parties to address their (common) interests and to discuss diverse health care topics.

Procedure on the request of data from the quality registration of the Dutch Institute for Clinical Auditing

Preface
The data collected by the Dutch Institute for Clinical Auditing (DICA) of the quality registrations are available for doing the scientific research.

Procedure for requesting scientific research
You can make a request for data at DICA by filling in the 'application form'. On the DICA website you can check under 'paying research requests' which research has already been performed on your subject. The application is judged against the criteria as drawn up by the Privacy Committee. The application is then assessed by one of the members of the Clinical Audit Board (CAB) of the quality registration concerned, supported by an employee of the DICA scientific office. The quality of your application determines the probability of data access..In some instances the DICA Methodological Council is asked for advice on this matter. Only the data that are relevant to the research question can be provided. Note: it is not possible to ask the complete list of variables.

Who can submit an application?
The submission of an application is reserved for participants in the relevant quality registrations and members of the Methodological Council with regard to the development of the methodology.

How should the application look?
This contains the following information:
o Request form.
o Ticked list of required variables (can be downloaded from the website).
o If applicable: signed forms 'Consent to the opinion of third parties' (see page 2).

To whom should the application be addressed:
You can address your request to:
Onderzoek@dica.nl

Which quality registrations can a scientific application be submitted?
The Clinical Audit Board (CAB) of each quality registration determines whether the data is suitable for external scientific publications. You can find this list on the DICA website. Data can only be requested when it is already availble; this is determined by DICA in consultation with the CAB. It is not intended that research questions should be submitted on data that will be added to the audit in the future.

You can request data for an entire year?
Full data of one yea, is only avaible at the end of the calender year. This is when the transparency portal closes. This data is avaible from March onward. So in March 2019, the full data of 2018 is complete. If quality registration does not yet participate in the policy portal, the data will be available earlier.

How many publications can you deliver from one research request?
With the data from one data request, one scientific research paper can be submitted. If you would like to write a second article, you must submit a new application, by a reduced rate.

How is the anonymity of hospitals guaranteed?

No hospital nformation is provided when distributing data scientific publications. If anonymity is not desired, the hospitasl must give separate permission for providing additional information via the form 'Permission to notify third parties'. You are responsible for these permissions yourself.

How is the anonymity of patients guaranteed?
No name and address details are provided when distributing data to advertisements. This indirectly identifying information is gender and year of birth. Depending on the issue, birth year can be converted to classes of years. The DICA Privacy Committee also oversees this. The data file must be deleted within a period of two months after the applicant's objective has been achieved.

Costs for reviewing the application
The quality registrations have the possibility to charge an amount of € 141.50 for reviewing the application.

Costs associated with the delivery of data
For the delivery, a huge amount is charged depending on the size of the extensive data set and the frequency of the delivery.

There are 5 types of applications:

• Simple request: € 250 (excl. VAT)
Requests with a maximum of 50 variables, one-time delivery.
• Average request: € 400 (excl. VAT)
Request for more than 50 variables, one-time delivery.
• Request extra variables: € 150 (excl. VAT)
Request for additional variables on an existing research request.
• Publication of second article: € 150 (excl. VAT)
If you would like to publish a second article of the data from an existing research application, a reduced rate applies.
• Extensive request: customized offer
Requests for which multiple deliveries are required, or separate requirements for calculations, constructions and the like.

What do you receive from DICA?
An encrypted and secured database with raw data (so no calculated variables or analyzes); this is a .csv file.

How does the procedure work after my application?
You will receive a response within two weeks and an assessment of your application within eight weeks.If the application must be submitted to the Methodological Council, an additional four weeks are added. After approval a contract is made.

When does a request expire?
If the research request has been approved by DICA, you will actually receive the data. There may be uncertainties about the application; in this case the coordinator will then contact you. If you do not respond to the questions within 3 months, the application will be canceled. You must then submit a new application.

After publication
A draft of the publication must be sent to DICA, after which it will send to the scientific committee of the relevant quality registration for assessment.