



## Developing a national quality registry for hand surgery: challenges and opportunities

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- The Scandinavian National Healthcare Quality Registries (NQRs) have brought about considerable improvements since their introduction in the 1970s.
- One such registry – HAKIR ('hand surgery') – was established in 2010 and was likely the first NQR for hand surgery.
- Patient-reported outcome and reoperations due to post-operative complications are registered in HAKIR, as well as hand function in selected groups of surgical procedures.
- Creating simple logistics for collecting data and careful planning are important factors when establishing a new NQR.
- Continuous surveillance of data validity and coverage are crucial for success.
- With perseverance, large databases for clinical research can be created, along with the establishment of national multi-professional collaboration in healthcare improvement work.

**Keywords:** quality registers; healthcare quality; hand surgery; orthopaedic registries

Cite this article: Arner, M. Developing a national quality registry for hand surgery: challenges and opportunities. *EFORT Open Rev* 2016;1:100-106. DOI: 10.1302/2058-5241.1.000045.

A Swedish national healthcare quality registry (NQR) may be defined as an archive comprising individualised data concerning patient problems, medical interventions, and outcomes following treatment.<sup>1</sup> A helpful precondition in Sweden is the issuance of an individualised social security number which identifies the date of birth for each citizen, a procedure that was introduced in 1947. Non-voluntary health data registries were established during the 1950s to 1970s, for example the Swedish Cancer Registry in 1958,<sup>2</sup> the Swedish Register of Congenital Malformations in 1964<sup>3</sup> and the Swedish Medical Birth Register in 1975.<sup>4</sup> The latter two registries were initiated after the thalidomide catastrophe in Europe in the early 1960s. About forty years ago, in 1975, the Swedish Knee Arthroplasty Register (SKAR)<sup>5</sup> was

established following an initiative by the Swedish Orthopaedic Association and can probably be regarded as the first NQR in the world. It was soon followed by the Swedish Hip Arthroplasty Register in 1979.<sup>6</sup> Registering all joint prostheses that had been implanted and removed led to the achievement of significant improvements over the years.<sup>7,8</sup> Sweden has one of the lowest revision rates for knee and hip implants in the world.<sup>9,10</sup>

The registry and follow-up programme for children with cerebral palsy, CPUP<sup>11</sup> was started on a small scale in 1994 and has resulted in very significant improvements for this patient group.<sup>12,13</sup> Spastic hip dislocation occurred in 8% of all children with cerebral palsy (CP) in Sweden before the establishment of CPUP – the same level as in most Western countries. Through standardised follow-up and early interventions (spasticity management and preventive surgery), hip dislocation in children with CP was reduced to 0.5%, and these results have remained stable over ten- and 20-year periods.<sup>12,13</sup>

NQRs have been implemented in many other fields of health care in Scandinavia. There are at present about 100 NQRs that receive central funding in Sweden and over 50 in Norway.<sup>14</sup> Many large patient groups within the Swedish healthcare system are followed by different NQRs, e.g. those within the fields of cardiology,<sup>15</sup> diabetes<sup>16</sup> and stroke.<sup>17</sup>

To our knowledge, there has been no previous NQR for specialised hand surgery anywhere in the world. Hand surgery has been an independent speciality in Sweden since 1983, distinct from orthopaedic and plastic surgery. There are seven hand surgery departments at university hospitals in Sweden, performing all kinds of hand surgery including that relating to acute hand trauma – such as microsurgical reconstructions and joint, tendon, ligament and nerve reconstructions – as well as paediatric hand surgery. Specialised hand surgery in private practice has expanded in recent years, especially in the three largest cities. The private units most often only treat elective cases in out-patient care.

In 2008, a project aimed at establishing a NQR for hand surgery in Sweden was initiated by the Swedish Society for Surgery of the Hand. In February 2010, the registry (HAKIR) opened for the first registrations at the hand surgery department at Södersjukhuset (Stockholm South General Hospital). Since 2014, all seven hand surgery

**Table 1. Experiences of developing a new surgical NQR**

- Discuss, inform and consolidate the project in national speciality groups – get consensus for the need for a NQR.
- Decide on a few primary goals for the new registry.
- Plan the logistics for collecting data – minimise the work effort involved at each step; utilise all available staff and reduce the participation of surgeons in the registrations; and ensure that data is registered without delay – in the operating room, at the patient visit to the clinic, at the therapy visit, etc.
- Plan follow-up routines for data coverage, completeness and validation.
- Collaborate with a professional IT service for the design and maintenance of the registry platform. Establish secure data management, including login to the registry.
- Appoint a central registry coordinator (not a surgeon) – crucial to the long-term durability of the registry. Continuous support and encouragement to all participating departments is vital.
- Start simple – only include variables that are easy to collect. Expanding the registry over time is much better than gathering incomplete data.
- Include all healthcare staff (nurses, therapists, secretaries) engaged in the care of the patients – listen to their advice concerning effective registration routines.
- Start small – one, or only a few, departments first, then expand when routines are efficient, the IT platform is working, and the data collection is complete.
- If there is funding, support work regarding data collection at a departmental level; assign local coordinators.
- Provide feedback on results and coverage to participating departments. Meet nationally in inter-professional groups for discussions.

hospital departments have been participating, as well as two private units. The main topic of this review is to describe the process of implementing a novel NQR for hand surgery.

## The initial phase

Learning from other NQRs, the initiators of HAKIR were aware that thorough planning was crucial to the establishment of a new registry. Some practical tips are listed in Table 1. The involved medical professions have to agree on the aims of the registry, and considerable motivation is required to spend time and effort throughout the start-up process. The support of heads of departments is essential, aside from fulfilling national legal requirements for handling personal patient data. Regarding aims, it must be emphasised that the primary focus for an NQR is to improve health care, since many surgeons tend to focus primarily on research. The main concept for quality registries is that registered data should be used as directly as possible in the care of patients, e.g. by detecting complications and improving treatments. Enabling research is another important aim for NQRs, but first, valid and reliable data on large populations have to be collected, and this work requires time and endurance. The primary aims for HAKIR are presented in Table 2.

In contrast to the older orthopaedic NQRs, a web-based design was agreed upon for HAKIR at the start. Each participating unit has complete and direct access to their own data online. The web-based design demands a secure log-on function, which is achieved through personal e-identification certificates – so-called ‘SITHS cards’ – for each user, bank-security data storage, and handling of all data.

## Registry variables

In the author’s experience, optimism is common in the initial discussions when starting a new registry. There is a significant risk of making registrations too complicated and impossible to implement, leading to incomplete data collection. An important tip is thus to ‘start simple’ and only include variables that are easy to collect. It is much

better to expand the number of variables when the logistics of the registry have been established. We, however, decided to register *all* operated patients at the participating units because this was easier to realise than to consider inclusion/exclusion criteria for each patient, even if some patients would not be followed up with a questionnaire. When registering all operations at each unit, comparisons with monthly hospital production statistics can be conducted, which makes it easier to follow and minimise data-loss.

Focus from the start should be to make registrations a part of clinical routine and as work-saving as possible, especially for busy surgeons. In HAKIR, the surgeons only play a small role in the collection of data, most of which is carried out by nurses and hand therapists.

HAKIR includes two steps: basic registration for *all* operations and extended registration as a voluntary add-on. The work flow for these two parts is presented in Fig. 1.

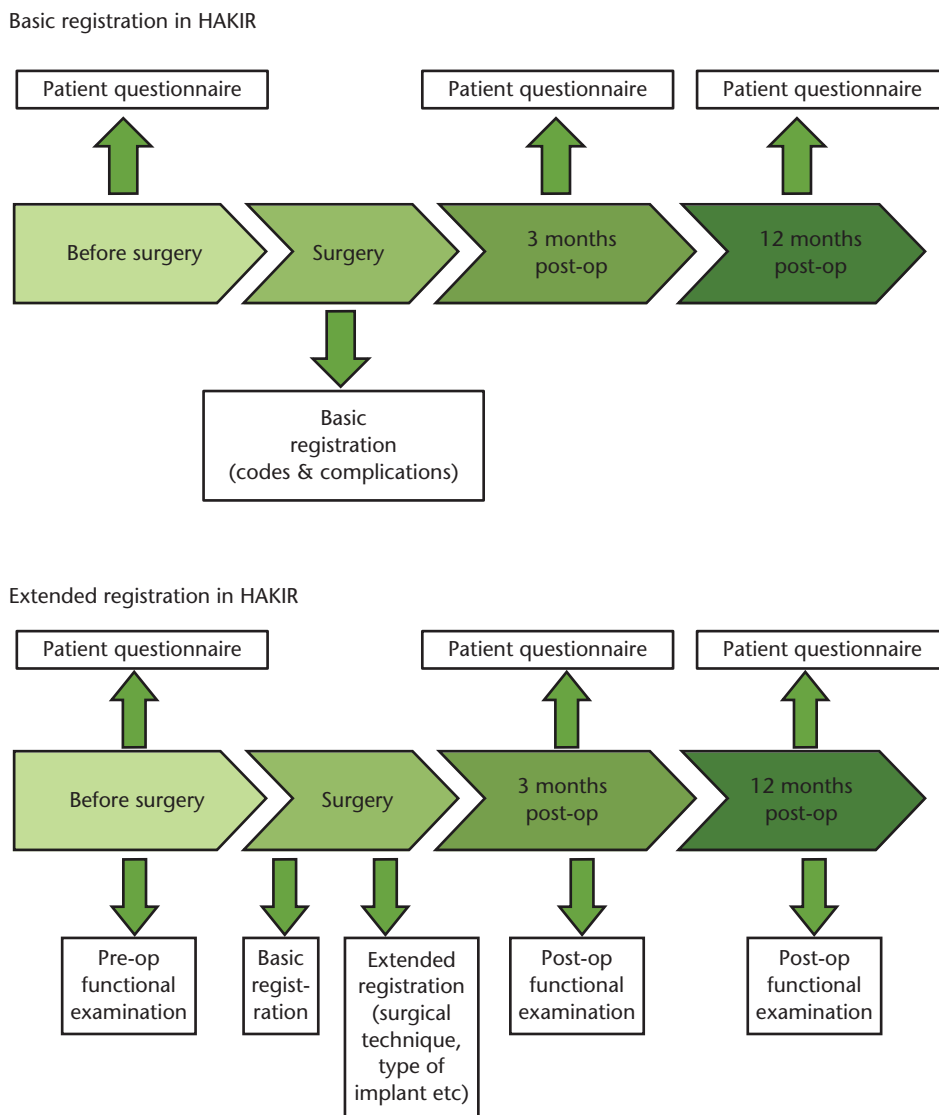
## Basic registration in HAKIR

Patients scheduled for hand surgery receive written and oral information about HAKIR. Patients with major hand trauma who undergo urgent surgery are informed about HAKIR as soon as possible after the operation. Hospital staff enter the patient’s details into HAKIR by registering the login credentials and social security number for each patient, a procedure that takes just a few minutes. Stickers with login credentials are attached to the information leaflet that is handed to the patient. According to legal requirements for NQRs in Sweden, all patients are informed that they can opt out of registrations and that their information can be erased from the registry at any time if they wish. Patients themselves enter their personal social security number, as well as their mobile phone number and email address, into the registry. This information is sent electronically – separately from the patient questionnaire.

After sending the file with the personal information, the patient can complete the questionnaire online from the website. In HAKIR we issue one pre-operative and two

**Table 2. Primary aims for the National Quality Registry HAKIR**

- To improve healthcare by continuous and standardised follow-up of results of hand surgical treatments, including patient-reported outcome.
- To help early identification of treatment methods with poor results, in order to minimise post-operative complications and improve care.
- To improve pre- and post-operative information to patients and increase patient participation in surgical decision-making.
- To create a large, valid and reliable database for clinical research.



**Fig. 1** Work flow for basic and extended registrations in HAKIR. All performed operations at each department are included in the basic registration. Extended registration can be added for selected types of operations, e.g. surgery for flexor tendon injury, joint implants and osteoarthritis of the thumb. Patients aged under 16 years, or with cognitive problems, or undergoing repeated surgery are not required to fill in the questionnaires.

post-operative questionnaires at three and twelve months, respectively. Patients with cognitive problems, and children under 16 years, are at present not required to fill out the questionnaires.

At surgery, the nurses log in to the registry with their personal SITHS card and enter the relevant codes for diagnoses (ICD10)<sup>18</sup> and surgical procedures (KKÅ97)<sup>19</sup> electronically in the operating room. These codes are already used for all surgical procedures in Sweden for the

purposes of hospital statistics and for reimbursement. If the operation is a reoperation, it is registered as to whether this was due to a post-operative complication, after consulting with the surgeon. Examples of complications that can be registered are: post-operative infections, tendon ruptures, arthroplasty complications, and nerve injuries. Definitions of complications have been discussed within the Swedish Society for Surgery of the Hand to ensure the highest possible level of consistency among registrations.

## Extended registration in HAKIR

For selected types of operations, extended registrations can be performed as an add-on feature. Protocols for ten different types of surgery are available in the registry, such as surgery for thumb osteoarthritis, flexor tendon lacerations, median and ulnar nerve injuries, Dupuytren's contracture and joint arthroplasties. In the extended registration, the surgeon has to specify the surgical method in more detail, such as the type of tendon suture, implant and tendon interposition method. This standardised surgical protocol is completed either online, or on paper in the operating room by the surgeon.

In the extended registration, patients are also requested to attend a physical examination before their operation and at three and twelve months post-operatively, usually as a part of regular follow-ups after surgery. These examinations are conducted by the hand therapist and include, for example, range of motion and grip strength. Hand therapy regimes can also be further specified in the protocol. Measurements are performed and documented according to a national measurement manual developed by hand therapists within the HAKIR project and freely available on the HAKIR website.<sup>20</sup> Radiographic variables, for instance non-union of a fusion or signs of loosening of a joint prosthesis, can also be registered in some of the extended protocols. At present, only five of the seven hand units now incorporate extended registrations, but we hope that this type of registration will be expanded to all units within one to two years. Extended registrations will provide data for comparing different surgical and rehabilitation methods, both for improvement work in healthcare and for use in scientific studies involving large volumes of patient data.

## How to collect patient reported outcome measures in an NQR

The Scandinavian arthroplasty registries did not include patient reported outcome measures (PROMs) until after several decades of operation, and the methods for collecting this data vary from paper questionnaires to web-based systems.<sup>5,6</sup> In HAKIR, we decided from the outset that PROMs were an important part of following up results, but that we needed a completely web-based design incorporating an electronic form of PROM data collection to be able to handle large volumes of data. We decided upon the QuickDASH questionnaire<sup>21</sup> since it is, at present, the most accepted type of questionnaire in terms of evaluating treatment results in hand surgery. A need for collecting additional information – especially regarding pain and ache symptoms – was found necessary since these symptoms often constitute the main indications for surgery. We also wanted to include questions on patient satisfaction with treatments and care, so these were added to the questionnaire. In total, the HAKIR questionnaire consists of eight questions on symptoms, eleven QuickDASH questions, and

two post-operative questions on satisfaction. The questionnaire is available in English on the website.<sup>20</sup> All variables, including the QuickDASH total score, range from 0 = no, to 100 = maximum symptoms or disability. Patients fill out the same questionnaire before their operation, and at three and twelve months after surgery.

A system of automatically sending out post-operative questionnaires from the registry to the patients was developed, initially via SMS text to the patients' mobile phones. After analysing the response rates however, we found that only around 30% of respondents had completed the web-questionnaire. After changing the delivery method to email plus a reminder SMS, we have now attained a response rate of between 50% and 60%, which is generally considered to be an acceptable response rate for online surveys.<sup>22</sup> Some patients and some departments still wish to use paper questionnaires, which necessitate a considerably greater work effort and higher costs. No manual handling is required for sending out the web questionnaires, and our goal is to render HAKIR completely paper-free within two years.

## When the registry is running

As soon as a department initiates registrations, there will be a demand for data feedback. The best option is if the members of each department have full online access to their own data and are able to print simple reports themselves. We advise planning for data reports from the outset and making them as flexible as possible to meet the different requirements of the different users, e.g. department heads, coordinators and patients. HAKIR has just recently developed a dynamic report showing aggregated results of flexor tendon surgery presented openly on the website.<sup>20</sup> Sometimes, surgeons or other staff request reports of results, when they, in fact, have registered very little, or incomplete, data. Reports of data coverage and completeness are therefore often the first reports that must be available.

One very beneficial form of support when running an NQR is a national coordinator and a national registry group, which preferably should be multi-professional. In the case of HAKIR, therapists and nurses have been the strong driving force in its implementation. The interest among surgeons varied initially, but has increased considerably as results have been presented.

Funding is of course required for the work involved in designing, implementing and operating an NQR, but in fact most of the Scandinavian registries have established themselves with no extra funding, through the work of enthusiasts spending time out of regular working hours. For long-time survival and expansion of the registry, however, regular funding is required. HAKIR was started at the same time as a five-year publicly-financed venture on NQRs in Sweden (70 % national government, 30% county councils), which has helped considerably in the rapid development of the registry.

## Achievements to date

The HAKIR project began at the hand surgery department in Stockholm in 2010 and has, over five years, expanded to include all seven hand surgery departments in Sweden. Since the start on 1 February 2010 until 30 November 2015, almost 60 000 hand surgical operations have been registered, now increasing by approximately 1300 operations each month. All departments that have participated for more than one year fulfil our goal of registering >80% of performed operations. The proportion is calculated by comparing registered data with hospital statistics, and data coverage for each department is openly presented on the website.<sup>18</sup> The goal cannot be set at 100% since some operated patients are of other nationalities, have protected identities, or have declined participation in the registry.

Since the outset up until 30 November 2015, 38 263 patient-reported questionnaires have been registered, of which 14 822 had been registered before their operation, 11 172 at three months' follow-up, and 8 275 at twelve months' follow-up. These large volumes of patient-reported outcome data can be used for multiple purposes. By analysing the QuickDASH and symptom scores for large diagnostic groups before operation, indications for surgery can be evaluated. By comparing pre- and post-operative scores, the results of different treatment methods can be compared from the patient perspective. Some examples are provided below. Another use of PROM data is to improve pre-operative information to patients, and for this purpose a report of aggregated data is published on our website,<sup>20</sup> presenting the responses of pre- and post-operative questionnaires for seven common operations, including surgery for carpal tunnel syndrome, thumb osteoarthritis, Dupuytren's contracture, and trigger finger. Patients scheduled to undergo these surgeries can access information beforehand relating to other patients' experiences of aches or pains, how their grip strength has been affected, and so on, before and after surgery. The data is automatically updated with more data each month and is openly available on the website.

Registration of reoperations caused by post-operative complications has given useful follow-up information to the participating units, and reports are issued monthly to the department heads. In annual reports for 2013 and 2014, post-operative infection was shown to be the most common complication leading to reoperation, though at 0.6% the rate was low.<sup>20</sup> The second most common complication was osteosynthesis-related problems, followed by scar adhesion/joint contracture after previous surgery. In 32% of reoperations due to complications, the primary surgery had been performed at another hospital, i.e. they were external complications. It should be emphasised, however, that only complications that have led to a reoperation are registered in HAKIR.

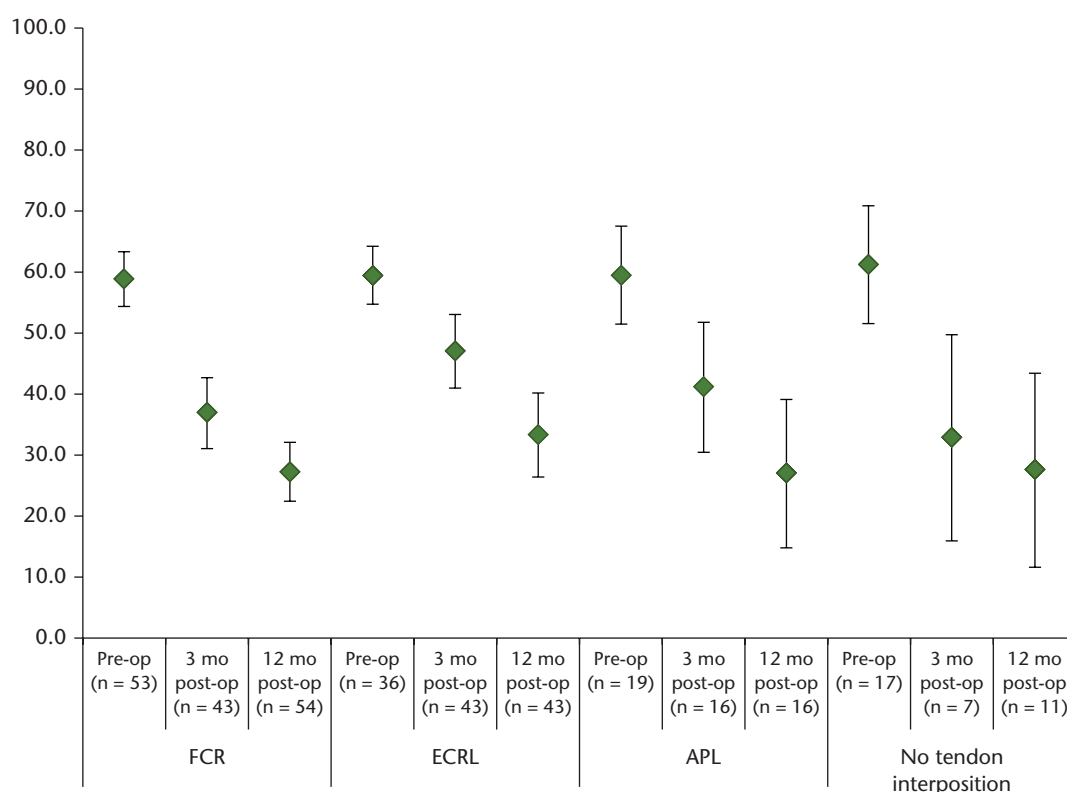
To date, the details of 651 operations and 1134 pre- and post-operative functional follow-ups have been

recorded for thumb osteoarthritis as a result of extended registration of surgery. We have found interesting geographical variations in the choice of surgical methods. At least three different types of tendon interposition methods are used in Sweden, as well as trapezectomies without tendon interposition. The results were presented in the 2014 annual report.<sup>20</sup> The mean QuickDASH score in the general population is reported to be between 5 and 22, depending on age.<sup>23</sup> The mean pre-operative QuickDASH score in patients scheduled for surgery for arthritis of the thumb, and registered in HAKIR, was approximately 60 before the operation, decreasing to 30 one year after surgery (Fig. 2). The minimal detectable change using the QuickDASH questionnaire is reported to be 15.9 points.<sup>24</sup> Thus, the entire group of thumb arthritis patients seem to have benefitted from the surgery. We still have too few one-year responses to analyse differences in patient-perceived results for different surgical methods, but all the examined methods seem to reduce disability (see Fig. 2). The score for pain at rest was reduced from approximately 50 to 10 (score 0-100) one year after surgery for arthritis of the thumb, meaning that the majority of patients were free from this type of pain. Pain during activities using the thumb, however, remained rather high, with a mean of 38. The data displays large variations in individual patient-perceived outcomes. A significant variation in results between individual surgeons was also noted, with mean QuickDASH scores varying between 4 and 38 and resting pain scores between 3 and 63 one year after operation for patients operated on by different surgeons. These interesting results will be followed and analysed further. With time, scientific studies can be performed on large volumes of patient data comparing the different methods.

To date, 569 flexor tendon sutures in zone II have been registered in the extended registration and 372 functional follow-ups. Thirteen per cent of the injuries included more than one finger, and in 44% there was also a digital nerve injury. The FDP (flexor digitorum profundus) tendons were most often sutured with a four-strand loop suture, with some local variations. Rehabilitation regimes varied between departments, early active mobilisation being the most commonly used method. Overall, the rupture rate was approximately 2%, and measurement of active motion at the distal interphalangeal (DIP) joint corresponded to a mean of 50 degrees one year after operation (annual report data 2014 available on webpage<sup>20</sup>). The time between injury and surgery varied between a mean of 1.8 and 6.6 days for the different departments. We will examine whether this delay had any importance for the results of tendon suture. A dynamic report of the results of flexor tendon sutures is available on the HAKIR website.<sup>20</sup>

## Conclusion and future opportunities

The possibility of creating an NQR is of course strongly dependent on the conditions and legislations of different



**Fig. 2** QuickDASH pre- and post-operative scores for patients who underwent a trapezectomy, with or without tendon interposition, for arthritis of the thumb. Results from the HAKIR questionnaire as reported in the annual report for 2014. FCR, flexor carpi radialis; ECRL, extensor carpi radialis longus; APL, abductor pollicis longus. n indicates the number of responses. 0 = no, and 100 = maximal perceived disability from the hand and arm. Error bars show 95% confidence intervals.

countries. In Scandinavia, personalised social security numbers, as well as political and legal acceptance for collecting individualised data in health care, have created the foundation for NQRs. Such registries have led to considerable improvements in health care and have provided a broad base for clinical research on large volumes of patient data. Complete registrations of joint arthroplasties have prevented the widespread introduction of joint implants with poor results in Sweden, but hand arthroplasties have so far not been included in the Swedish arthroplasty registries. Thus the introduction of HAKIR, also for this reason, represents a long-awaited complement. An important aim for NQRs is the sentinel function of detecting poor methods at an early stage and preventing their widespread use.

The experience of the hand surgery NQR HAKIR is that the inclusion of patient-reported outcomes, in combination with complete registrations of all reoperations and selected follow-ups of functional variables, can provide a valuable basis for improvement work in healthcare, as well as a unique future source for clinical research. After collecting pre- and post-operative data for five years, many interesting results regarding outcomes following hand surgery have already been gathered. Multi-professional collaboration and the development of work-saving logistics are essential for success. Creating a new NQR demands patience, endurance and time.

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#### CONFLICT OF INTEREST

None declared.

#### FUNDING

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

#### LICENCE

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