**BACKGROUND**

The annual global dental implant market is estimated at around 12–18 million implants sold (Figure 1), representing more than 100 commercial brands. In Europe alone, the annual market has been estimated at 5.5–6 million implants (Figure 2). Precise figures are not publicly available. Each brand offers a number of different implants, with various macro- and micro-characteristics and material composition. In total, several hundred million patients have been provided with dental implants over the last decades (Figure 1). Few studies have been published representing long-term outcome of treatment performed in everyday practice representing a mixed patient population.

Rapid development of new implants (Figure 3), surgical and prosthodontic materials and procedures and the introduction of these innovations to the clinic, with no or limited scientific evidence, are factors behind the initiative of an implant quality register.

As an association for professionals, the EAO has felt the responsibility to contribute to improved quality of care. The philosophy behind the initiative is to create a voluntary database for learning and quality improvement, not for supervision.

Almost 100 years ago, Ernest Ameron Codman, a Boston surgeon, stated “The common sense notion that every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire: - if not,
why not?—with a view of preventing similar failures in the future* (Codman, 1934).

Quality registers have been developed within health care to fill the gap between patient records and primary monitoring systems. These quality registers collect information on the individual patients’ possible problems, interventions, and outcomes after treatment. The vision for the quality registers is that they will be “used in an integrated and active way for continuous learning, improvement, research, and management to create the best possible health and care together with the individual” (Peterson et al., 2015). Data are collected so as to allow the data to be compiled for all patients and analyzed at the unit level or aggregated at higher levels. Principles for starting and maintain high-quality registers have been well described previously (Ejerhed, 2013; Levay, 2016; Nelson et al., 2015). The feasibility of registries is influenced by national policies including reporting requirements and patient data regulations.

Following a review of the National Quality Registers in Sweden, a report was published: “The Goldmine in the healthcare” (Rosén, 2010). It was concluded that quality registers saves lives and improves the quality of life of patients. In the report, several examples were presented: open comparisons in the care of myocardial infarction and orthopedics have led to improvements, better and more durable prostheses are used in hip replacement, improvement in stroke health care, children with cancer live longer, treatment results following surgery of inguinal hernia has improved, the number of intraocular infections following cataract surgery has been reduced by 50% (Larsson, Lawyer, Garellick, Lindahl & Lundström, 2012). It was also shown that the registers can be used to improve the participation by the patients, long-term assessment of risks and evaluation of initiatives to improve treatment. Problems were also identified, including double-registration of the same data both in patient records and quality registers. It was concluded that more reliable indicators for comparison of results should be developed. Examples of registers presenting outcome of research include diabetes (Peterson et al., 2015, Hallgren Elfgren, Grodzinsky and Törnvall (2016), rheumatology/rheumatoid arthritis (Eriksson, Askling & Arkema, 2014; Ibfield, Jensen & Hetland, 2016; Ibfeldt et al. 2017), stroke (Varmdal et al., 2015) and numerous more. The search term “quality register” in PubMed results in 15,691 publications listed in February 2018.

At the top level in the evidence hierarchy in medical and dental implant research, today is the randomized controlled trial (RCT). Shortcomings often include small sample size, too short follow-up, patient selection, cost, time, and resources available. Furthermore, the external validity of the research findings can be questioned. This may limit the value of many RCTs. Unique opportunities to monitor patients and for evaluation of quality and outcome of treatment have gradually developed with the introduction of quality registers. Given a large participation, the registers will allow for the possibility to detect and analyze unusual phenomena like rare side effects and complications and the influence of rare baseline characteristics (Lauer & D’Augostino, 2013; Martling, 2015). In our special field of interest, a new dental implant or prosthetic device may only be used in few numbers by individual dentists, but by adding all connected clinicians, the total number of devices may be substantial and thus allow for relevant analyses. Quality registers have a great potential to show long-term risks with medical products (including dental implants). Surgical procedures have been considered especially troublesome when conducting randomized clinical trials, because surgeons have their own preferences, education, training, and surgical skills. This may also be valid for the prosthetic part of the treatment. Procedures may develop and change

FIGURE 1 Estimated figures for the annual sales of dental implants at the Global market and accumulated total numbers of implants sold globally. Exact figures are unknown, but the figure illustrates a possible trend

FIGURE 2 Estimated figures for the annual sales of dental implants at the European market and accumulated total numbers of implants sold in Europe. Exact figures are unknown, but the figure illustrates a possible trend

FIGURE 3 Examples of dental implants that are installed in patients. Many of the implants have no or limited controlled follow-up from everyday clinical practice
over time. Using quality register data and stratifying for time, there is an opportunity to study the introduction of new techniques. Patients of different ages, socioeconomic background, and various comorbidity are all included in the quality registries. Patients are treated both by skilled and less experienced clinicians. The patients in the registers often reflect clinical routine without selection: that is, "the real world."

Worldwide, hundreds of registries exist. In the United Kingdom, more than 50 clinical audit programs are available. Over 110 federally qualified registries report quality metrics in the United States. Sweden has more than 100 national quality registers (Nelson et al., 2016). A review of 103 Swedish Healthcare Quality Registries was recently published (Emilsson, Lindahl, Köster, Lambe & Ludvigsson, 2015).

2 | SOME SELECT EXAMPLES OF QUALITY REGISTERS

2.1 | RIKSHÖFT The Swedish hip fracture register

The development of quality registers in the healthcare sector was started with a register for knee prostheses in 1975 and a hip prostheses register in 1979. The Swedish hip fracture register [http://www.rikshoft.se] started in 1988. Scotland was the first country outside Sweden to adopt the idea in 1993 (Hommel & Bååth, 2016). The hip replacement registry allowed researchers to study over time specific hip prostheses, including postmarket surveillance of individual implant performance, surgical procedures, and units were associated with the fewest reoperations (Ovretveit, Nelson & James, 2016). The findings were regularly reported to the orthopedic surgeons. In 10 years, the hip reoperation rate was reduced from 10 to around three percent. The Swedish Hip Arthroplasty Register (SHAR) has been important to identify implants that have not performed well, consequently, they have been removed from the market (Cnudde et al., 2016, 2017). Of late, the Finnish Arthroplasty Register reported on significant differences in the outcome between cemented and cementless hip replacement in the octogenarian population. The increased risk of early revision using one technique was particularly evident in women (Jämsen, Eskelinen, Peltola & Mäkelä, 2014). Hip fracture registers in Europe are also available in Ireland (Irish Hip Fracture Database [IHFD]), United Kingdom (National Hip Fracture Database [NHFD]) and in development in Spain (Spanish Registry of Hip Fractures). It should be recognized that despite decades of clinical and register research there is no consistent definition of what can be considered a successful joint replacement. Furthermore, outcome measures are not harmonized (Cnudde et al., 2016).

2.2 | The European registry of quality outcomes for cataract and refractive surgery (EUREQUO)

In 2004, the European Society of Cataract & Refractive Surgeons (ESCRS) initiated a register for outcomes of refractive surgery, the Refractive Surgery Outcomes Information System (RSOIS). The purpose was to record outcomes of surgery and to improve quality of the related procedures. The background to the initiative was growing health tourism and increasing patient complaints reported by mass media in some countries. It was considered that the patient complaints were associated with inappropriate indications and surgery outside the protocol leading to suboptimal outcome of surgical intervention. In 2007, the ESCRs applied for a EU grant to establish a European register to improve quality in cataract and refractive surgery. The application was successful and a European web-based register for cataract and refractive surgery, The European Registry of Quality Outcomes in Cataract and Refractive Surgery (EUREQUO) was established in 2008. The aim of the registry is to improve treatment and standards of care for cataract and refractive surgery and to enable benchmarking using a reference database and for surgeons to enter and analyze their own outcomes (Lundström et al., 2014, 2015; Manning et al., 2015). More than 2.5 million cataract surgeries and 105,000 refractive procedures have been included in the database (personal communication M Lundström). The number of reported surgical procedures increases with around 4,000 cases annually. It is reported that the frequency of surgical complications and visual outcomes varies with the different surgical procedures.

2.3 | The Dutch National Breast Implant Registry

It is estimated that 1%-3% of all woman in the Netherlands have breast implants. Problems have emerged with a variety of breast implants with consequences for the patients' health. In 2010, the PIP (Poly Implant Prothèse) implant scandal, with rupturing and leaking implants, clearly showed the limitations in the available data and revealed the lack of a system to even "track and trace" the patients. A recent report by the Dutch Institute of National Health reported a lack of compliance of breast implant producers to CE requirements (Rakhorst et al., 2017). The need for an independent implant registry was expressed by the medical profession. The Dutch Breast Implant Registry (DBIR) is an opt-out registry with a high capture rate. The Dutch consider their experience to be a shareware for others in starting a patient registry (Rakhorst et al., 2017).

2.4 | Swedish Quality Registry for Caries and Periodontal Disease (SKaPa)

This registry was initially launched in 2008. In 2016, a total of 1,069 public and 90 private dental clinics are affiliated, representing around 6.1 million individuals of the total Swedish population of 10 million. SKaPa receives information by automatic transfer of data on a daily basis from electronic patient dental records. Information on the patient level includes personal identifier, gender, age, living area, dental status, risk assessment for caries and periodontitis according to standard protocol. In addition, all dental care provided is registered related to the standardized Swedish coding system for
patient reimbursement. The registry allows for systematic evaluation of oral health and quality of dental care and supports clinical and epidemiological research (SKaPa). At present, it is not possible to automatically load data on implant characteristics.

2.5 Controlled Randomized Registry Research using data from quality registers

The RCT is considered a most powerful tool in clinical research. In particular, the huge mega-trials have influenced and transformed medical and dental practice. The complexity, expense, inadequate patient representativeness, and the hurdle to recruit a sufficient number of study participants has been highlighted to limit the ability to implement RCTs in many research areas of interest and clinical importance. Comparative observational registry studies have been questioned due to the lack of rigor of randomization (Lauer & D’Augustino, 2013). However, a new paradigm was recently introduced with the registry-based randomized trial. In TASTE (Thrombus Aspiration during ST-segment Elevation Myocardial Infarction) study, a large-scale trial was designed to answer an important clinical question, whether thrombus aspiration reduces mortality. Patients were enrolled from the national comprehensive Swedish Coronary Angiography and Angioplasty Registry (SCAAR). Using this already-existing high-quality observational registry, it was possible to quickly identify potential participants and to enroll thousands of patients to test and control intervention in limited time.

Patients undergoing PCI (Percutaneous Coronary Intervention) were randomly assigned to manual thrombus aspiration followed by PCI or to PCI only. The primary endpoint was all-cause mortality in 30 days. The results showed that routine thrombus aspiration before PCI as compared with PCI alone did not reduce the mortality among patients with this type of myocardial infarction (Fröbert et al., 2013). However, a new paradigm was recently introduced with the registry-based randomized trial. In the TASTE (Thrombus Aspiration during ST-segment Elevation Myocardial Infarction) study, a large-scale trial was designed to answer an important clinical question, whether thrombus aspiration reduces mortality. Patients were enrolled from the national comprehensive Swedish Coronary Angiography and Angioplasty Registry (SCAAR). Using this already-existing high-quality observational registry, it was possible to quickly identify potential participants and to enroll thousands of patients to test and control intervention in limited time.

Patients undergoing PCI (Percutaneous Coronary Intervention) were randomly assigned to manual thrombus aspiration followed by PCI or to PCI only. The primary endpoint was all-cause mortality in 30 days. The results showed that routine thrombus aspiration before PCI as compared with PCI alone did not reduce the mortality among patients with this type of myocardial infarction (Fröbert et al., 2013). The controlled randomized registry-based research design may well be transformed to questions related to dental implant treatment, given that a high-quality implant register is established.

3.1 Technical issues

Modern scan technology allows for scanning of patient ID records and implant product packages. However, this technology is not yet readily available at most private or public clinics, thus making use of the advantage of scanning less feasible at the present time.

Two major alternatives seem relevant: a "stand-alone" system or a web-based system. Both systems are suggested to include the same parameters to be registered. Data transfer from the "stand-alone"-system requires manual downloading of anonymous collected data to the central unit for further analysis and feed-back.

A web-based system could be created for input and output of data. Individual patient data will be anonymous in the register.

3.2 Clinical issues

The validity of data generated by uncalibrated examiners may be questioned. However, this shortcoming may be of minor importance as a high number of clinicians will be expected to be involved. Thus, the probability of systematic errors should be low. Interrater reliability has been tested to be substantial to excellent (Varmdal et al., 2015).

In implant treatment, the goal is to achieve optimal aesthetic and functional results and no complications. Quality indicators will be selected to reflect these items. Output reports will be designed to allow the clinician to obtain statistics as frequency tables or graphs from the database via the web.

3.3 Patient-Reported Outcome Measures (PROM)

Patient-reported outcomes are important to gain understanding of patients’ views on the effect of treatment (Lindblad et al., 2017; Nelson et al., 2015). Both disease specific and generic patient-reported outcome measures (PROMs) are available. In addition, or as an alternative to PROM, also patient-reported experience measures (PREMs) are widely used. In common, PROM/PREM consists of a self-administered questionnaire and includes reporting of symptoms, functional ability and health-related quality of life. The administrative and respondent burden should be acceptable. Today many registries use web-based interfaces for patient self-reporting (Nilsson, Orwelius & Kristenson, 2016).

Until recently, it was often believed that the responsibility and capacity to define treatment outcomes and creating relevant measures rested largely with the health professionals. It is now appreciated that patients can offer valuable input also as research partners. Pioneering efforts in this area were made by the scientific organization for outcome measures in Rheumatology (OMERACT) to always involve people living with health conditions to act as collaborative research partners (Kirwan et al., 2017).

In the dental SKaPa registry, an initiative was made to further develop PROM in dentistry based on modern concepts of item response theory and the experience of the item-banking project PROMIS®. PROMIS is a US-based cooperative group of research sites and centers of excellence convened to develop and standardize patient-reported outcome measures across studies and settings (Alonso et al., 2013). By time, it seems relevant to adopt the outcome of this initiative also into the Dental IQ.
3.4 | Integrity and ethical issues

Handling of personal data in a registry is regulated by an EU directive—the Data Protection Directive (Directive 95/46/EC On the protection of individuals with regard to the processing of personal data and on the free movement of such data). In May 2018, a new resolution (GDPR: General Data Protection Resolution) will enter into force. It is likely that consent will be required to register patient data and the patient will have the right to have information erased from the register. Adequate safety for the protection of data must be guaranteed. The personal data in the Dental IQ will be anonymous to all parties except the reporting center, which will have the possibility to track data to a specific patient record and thus to a specific individual patient. No names or patient-identifying data will be stored in the database. If the data are used for clinical research, it is necessary to have prior approval from an Ethics Committee.

3.5 | Ownership

Each participating clinic will own its own data. It is understood that EAO owns the Dental IQ and is responsible for legal care of the collective database. EAO has the right to publish aggregated data and statistics from the total database.

3.6 | The industry

To support a positive development of the implant industry, the cooperation and interaction for clinical research with the dental profession need to be further explored. A well-functioning Dental IQ could create good conditions for clinical research in the dental implant field and allow for controlled testing and developing of new concepts and products. The quality register will allow for good possibilities to indicate long-term complications with different materials and procedures used in clinical everyday practice. Unlike clinical testing, the register can provide information of the outcome of treatment for all different patient categories. There is a legitimate concern that the impartiality of a register can be questioned depending on the cooperation with the industry. It is therefore important that all data and analyses are published and made public, regardless of the financing of the respective studies. Should studies not be published in scientific articles they should be published on the home page of the register. According to the
Swedish investigation on quality registers a general sponsoring from the industry without a defined return is dissuaded. It seems suitable that guidelines for the cooperation with industry and the register are provided and determined by the Board.

3.7 The National Quality Register for Dental Implants (NQRDI) as a template for a proposed Dental IQ

Attempts have been made in Denmark, Finland, and Sweden to establish National Quality Registers for dental implants. The success has been limited, with scanty participation. The Finnish Dental Implant Register has been maintained by The National Institute for Health and Welfare (THL) since 1994. Although several enthusiastic forerunners have reported data, very selective reporting was obtained. In Finland, it was found that approximately 76% of all implants placed in the years 2008 to 2010 were actually registered (Antalainen, Helminen, Forss, Sándor & Wolff, 2013). Suspicion of misuse of collected data has been presented as a factor contributing to the limited interest. A risk to be publicly designated as a less successful clinic or clinician was included in the presented objections. Nevertheless, the experience obtained forms a valid foundation for the creation of a European implant register. At an early open meeting with clinicians interested to participate in the Swedish dental implant register met with representatives from the very successful Hip Arthroplasty Register invited to share their experience and recommendations. It was suggested to register as few indicators as possible: "five indicators is a good number." It should then be realized that several meetings with different stakeholders (general dentists, specialists in oral surgery, prosthodontics and periodontology) had resulted in a long list—more than 60—"necessary" indicators. According to Swedish consensus, it was subsequently decided to offer two alternatives for registration: one basic Table 1 (14 parameters) and one extended Table 2 (40 parameters). All patients registered in the "extended" version were automatically also transformed to be included in the "basic" version of the national quality register. As automatic retrieval of patient records not was considered feasible this means that data must be entered manually into the designed web-forms. When designing the "basic" version the objective was that registration of an individual and the included procedures should take no longer than 2 min. Whenever possible preset alternatives should be made available in the common dropdown menu.

Proposals and recommendations by the Consensus Conference regarding a Implant Register is presented in a separate article in this special issue of Clinical Oral Implants Research.

ACKNOWLEDGEMENTS

The authors would like to gratefully acknowledge the excellent production of the schematic figure by Dr Jörgen Jönsson, Department of Dental Medicine, Karolinska Institutet, Stockholm, Sweden. The help by Staffan Larsson, Karolinska Institutet, with the composite implant image is also much appreciated.

CONFLICT OF INTERESTS

The authors report no conflict of interests in relation to the present article.

ORCID

Björn Klinge http://orcid.org/0000-0003-2100-2446
Kristina Bertil http://orcid.org/0000-0002-8279-7943
Anna Klinge http://orcid.org/0000-0003-2811-0722
Andreas Stavropoulos http://orcid.org/0000-0001-8161-3754

REFERENCE

Hommel, A., & Bäåth, C. (2016). A national quality registers as a tool to audit items of the fundamentals of care to older patients with hip...