Development and validation of the GynOp register's questionnaires and forms

Summarising 30 years of development and validation
of the Swedish National Quality Register of Gynecological Surgery (GynOp)

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GynOp

THE SWEDISH NATIONAL QUALITY REGISTER
OF GYNECOLOGICAL SURGERY

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Foreword

This report summarises the development and validation that has taken place in the Swedish National Quality Register in Gynecological Surgery (GynOp) since the register was established in 1994. The report will be updated regularly as new information arises, which is why it has been given a version number. This is the English version of the original Swedish-language report.

Background

In 1988, the very first laparoscopic hysterectomy was performed. In 1991, hysteroscopic endometrial resection began to be performed. The introduction of endoscopic[1] surgery began on a broad front, and in 1993 the Swedish Planning and Rationalization Institute of the Health Services (SPRI) organised a consensus conference on endoscopic hysterectomy. One of the main conclusions was that a national quality registers in endoscopic surgery should be established.

In 1992, the Swedish Society of Obstetrics and Gynecology (SFOG) formed a working committee for endoscopic surgery (Skopi-Arg). In 1994, Mats Löfgren, Jan-Henrik Stjerndahl (formerly Ohlsson) and Fredrik Nordenskjöld were working with Skopi-Arg when they were appointed by the Swedish National Board of Health and Welfare to investigate and create three national endoscopic surgery quality registers for hysterectomy, surgery of ovaries and fallopian tubes, and hysteroscopy. Funds were allocated to what would become one of the first 10 national quality registers. To that point, these were the only national quality registers, and there was limited experience and knowledge of the role they would play vis-à-vis clinics.

Several meetings were held with existing national quality registers, epidemiological experts and the Department of Computer Science at Umeå University to discuss methods and register technologies.

The three individuals above and the then Director General of the National Board of Health and Welfare, Bo Lindblom (also a pioneer in gynecological and endoscopic surgery), led the initial investigation in close collaboration with Skopi-Arg, where decisive decisions were made ahead of the planning work and consultations were held with SFOG's board.

Decision in preparation of creating the GynOp register (1994)

1. It was decided to create a single gynecological surgery register with independent sub-registers. This was intended to pool resources since they had so many variables in common, to avoid several different register platforms and to prevent the creation of islands.

2. Patient questionnaires pre- and postoperatively: Reason: patients know their own situation best. Measures were assumed to be curative, follow-up from the medical care system was only selectively targeted and there were no resources/reasons for collecting postoperative results through follow-up appointments. The literature of the time indicated that it was difficult to exceed 60% participation in routine follow-up appointments. For questionnaire studies, a response rate of over 70% was considered reliable [1]. The hypothesis was that a significantly higher response rate was possible if the questionnaire was sent from the treating clinic.

3. Physician forms were intended to primarily measure the assessments of the medical care system. Initially, physician forms were to have essentially the same variables as patient questionnaires, that is, a comprehensive questionnaire before surgery and a questionnaire for the follow-up appointment. There was widespread doubt as to whether patients could describe their situation correctly. This resulted in the physician questionnaire having an

[1] Endoscopy: The collective name for different types of keyhole operations, such as laparoscopy or hysteroscopy.

extensive list of variables which could then be reduced later based on the results. This was preceded by extensive discussions within Skopi-Arg as this approach contradicted the philosophy of using minimalist physician forms.

4. To reduce duplication of work, collected material was to be compiled into a useful text proposal to be included in the medical record and the post-operative questionnaires, if possible, were to serve as patient-specific follow-up.

5. A software that the clinics could use to register data, which produced a text that could be used for medical records. For most existing registers, clinics sent their paper forms to a central unit for registration. Paper medical records were used at the time, and the internet was not yet used by the general public. After an assessment of needs, UMDAC (Umeå University's data centre) was chosen as the IT supplier. In 2012, both patient questionnaires and physician forms became available online.

Patient questionnaires and physician forms

A working group within Skopi-Arg was appointed to draw up a specification of the questions to include in the patient questionnaires and variables in the physician forms. This work included formulating what is to be answered as clearly as possible and in the form of a proposal for the question.

The preoperative patient questionnaires were to include background factors related to the gynecological condition and general health data. The country's gynecological clinics were asked whether they had specific gynecological health declarations in questionnaire form. Of these clinic questionnaires, none had been validated with patients. The country's anaesthesia clinics were also asked if they had general health declarations in questionnaire form. There were anaesthesia questionnaires designed and used by physicians, but none of the questionnaire questions were reported to have undergone a validation procedure.

A common weakness of all the received questionnaires was that a significant number of the questions required open-ended responses, which cannot be not statistically processed. Literature studies were conducted, but no validated international questionnaires were found. The received questionnaires were used for domain specification.

The gynecologically specific questions were included in both preoperative questionnaires and follow-up that was to occur 6 months postoperatively. While validated questions regarding sexuality and alcohol and drug use were found, these were deemed too detailed to be relevant other than for study purposes.

The EQ5D questionnaire was considered too focused on the locomotor system and SF-36 is too detailed. Over time, these two have been reevaluated, but they have been deemed not relevant to GynOp's needs.

This work was mainly conducted in 1995.

Governing principles for questionnaires in GynOp

Validated and recognised instruments are required when introducing new questions/question areas. These instruments need to be customised for their use in daily clinical work, should be designed above all for research and study purposes, and should not be too comprehensive.

New questions need to be validated and tested for acceptance before being included in questionnaires. Individual questions may be validated separately, but for major changes, the questionnaire as a whole is to be tested. When changing individual questions, the previous version

should be considered to avoid loss of comparability over time. Reformulated questions should be used in parallel over a shorter period to ensure comparability.

The method for validation described in the chapter “Validation of questionnaires and data 1996–2000" is used by the Educational Measurements Unit at Umeå University and has been used for every revision of the questionnaires in GynOp since its inception.

Generally, questionnaires are used for sample questionnaires or studies and do not undergo regular review and validation while in use. In this respect, GynOp’s questionnaires are used differently. The questionnaires in GynOp are used regularly by participating clinics. As the majority of the questionnaires are read and assessed by attending physicians, systematic errors and misunderstandings are discovered and the validity and function of the questionnaires are regularly reviewed. This is the most dependable method of validation.

Validation of questionnaires and data (1996–2000)

Since the Swedish National Board of Health and Welfare had allocated funding, the Educational Measurements Unit at Umeå University was assigned the task to design and validate the questionnaire questions. The unit is also responsible for the design of the Swedish Scholastic Aptitude Test (SweSAT).

For the patient questionnaires, validity testing was conducted in four stages in 1995 and 1996. The test subjects were first asked to fill out the questionnaire. The test leader then went through the questionnaire with the test subject question by question to investigate how the subject had perceived each question and how it had been answered.

In the first step, the test subjects were medical care staff. In second step, they were patients in unspecified situations. In step three they were patients in the pre- and postoperative course of the interventions in question. Stage four was conducted in the same way as stage three, but at several hospitals spread across the country and at different types of hospitals (Skellefteå, Umeå, Sahlgrenska, Skövde, Varberg, and Södertälje). Stage four included 28 patients of 35 invited patients. Steps three and four were conducted by staff from the Educational Measurements Unit at Umeå University. For each step, the questions were adjusted based on the test results. The extent of the changes identified after step four was so insignificant that no further testing was deemed necessary.

Above all, steps three and four showed that patients perceived the preoperative questionnaire as relevant to their upcoming operation, which is why they were willing to accept such an extensive questionnaire and why they answered carefully. These patient opinions were reported. That the postoperative questionnaire was sent from the operating clinic and the responses were returned to the operating surgeon strongly contributed to the willingness to respond.

Testing revealed that patients had difficulty answering which diseases they currently have or have had. “How do I know that I don’t have, for example, high blood pressure or goitre when it hasn’t been checked.” “Someone at a health food store, an acupuncturist, an iridologist, etcetera told me that I have high blood pressure or diabetes.” These problems disappeared after reformulating the question from “Have or have you had” to “Has a doctor confirmed that you have or have had”.

The same testing procedure was performed with the physician forms, with step two being performed on participants at a Skopi-Arg meeting. Steps three and four were conducted at the same hospitals as described above.

Testing the physician forms was complicated. Like the test subjects, the doctors stated that it was difficult to follow the protocol, to first fill in the forms based on the most recent operation and relevant patient, then go through the questionnaire question by question to determine how the

respondent answered and why. A typical example was respondents only reading through the physician forms without answering the questions, and then discussing whether the questions were relevant and not whether the question could be understood and how it was answered. Pointing out the necessity of this procedure did not help. In step 4, four doctors at each clinic were to be interviewed with time set aside for the interview, but only 2–3 doctors would come and they were short of time. In total, only 3–4 complete interviews were carried out in step 4. The testing showed that it was felt that there were too many parameters to answer and that some of the most important ones were missing. The opinions varied significantly between the test participants.

The register was launched at nine clinics in January 1997 and was primarily designed to only track endoscopic surgeries. Within just a few months, this proved impossible. When the patients were scheduled for surgery, the method or operating surgeon had often not yet been selected. The final surgical method was often decided the day before surgery, which is why these patients were not included in the register. The solution was to include all relevant operations, regardless of which surgical method was chosen. This, in turn, offered opportunities for comparing methods.

A new version of the register was launched in May 1997. In the first year, nine clinics participated. By 1999, 23 clinics had joined. At that point, GynOp included hysterectomies and operative hysteroscopies (endometrial ablations). Initially, endometrial ablation was performed using hysteroscopy and a diathermic accessory, most frequently with a ball tip electrode. Today, endometrial ablation is usually performed using a separate instrument without the need for hysteroscopy.

Response rates

GynOp's software prints personalised questionnaires for patients with questions based on planned or performed surgery (the later applies to the follow-up questionnaires) and including a cover letter explaining that the clinic will assess the questionnaire responses. The letter is addressed from the planned or actual operating surgeon (depending on whether this is a pre- or postoperative questionnaire). The database tracks the date the questionnaire is sent, and a reminder is sent automatically if no response is received within a specified period. Questionnaires can also be printed without a name for manual processing, but then tracking to send a reminder is not possible.

Analyses were conducted in the autumn of 1999 on 1,931 operated patients from 23 participating clinics where the follow-up period had exceeded 6 months. Response rates were analysed after excluding patients judged by the attending physician as not suitable for questionnaires (4.1%). One clinic was excluded from the analysis because it only had a response rate of 36% due to poor questionnaire mailing procedures. Subsequently, 1,755 patients (1,658 hysterectomies and 97 hysteroscopic endometrial ablations) were included.

The response rate on preoperative patient questionnaires varied between 85 and 100% (mean 94.5%). Clinics with a response rate exceeding 95% (n=13) used a personalised questionnaire.

Preoperatively, there is rarely time to send reminders since the operation is scheduled to occur shortly. The preoperative questionnaire was printed using the software for 1,482 patients (86%) with a response rate of 97%. Of 20 core questions that all patients received, 91% had no more than two unanswered questions and 44% had all questions answered. The questionnaire had questions about caesarean section, both when asking about the number of pregnancies and deliveries and under questions on previous gynecological operations. Inconsistent responses were provided by 0.5% of the patients.

Fifteen per cent of responding patients reported difficulty in answering individual questions. The question of having had an endometrial resection (removal of the uterine lining) accounted for one-quarter of those who reported difficulties. It was common for patients who did not undergo an

endometrial ablation to interpret it as an abrasion. The second most common issue was patients clarifying an answer in their own words. The third most common issue was that patients did not understand the name for the disease or operation being asked about. Specifying the year of previous operations was also difficult for some respondents. Only 1.9% of questionnaires indicated that there were difficulties with several questions or that the respondent did not understand the questions or the language.

A personalised postoperative questionnaire was sent to 87% of patients. The response rate to the first questionnaire was 66%. After the first reminder, the response rate rose to 72%. The response rate was overall lower, 86%, for the patients who had or were scheduled for a follow-up appointment. Those who had not been to their follow-up appointment or did not have a follow-up appointment scheduled had a response rate of 92%. Clinics had a pronounced difference in follow-up appointment policy ranging between 5% and 100%.

Patients with a planned or completed follow-up appointment after surgery had a lower response rate for the postoperative questionnaire (6 weeks after surgery, $p < 0.001$). Eighty-eight patients (6.5%) had difficulty understanding questions, of which 81 provided written comments. These comments almost exclusively dealt with the difficulty in specifying the exact number of days of pain relief or return to normal daily activities and the date when the patient felt they were fully recovered. There were two comments that the language was difficult to understand.

Complications

Initially, the division into mild or serious complications was not included in the postoperative questionnaire. There were some predefined response alternatives, such as fever, surgical wound infection, discharge, abdominal infection, bleeding, urine leakage and the alternative “other” as well as an open-ended response field where patients were asked to describe what happened. In 1,352 postoperative questionnaires, patients provided 433 (32%) comments regarding postoperative complications. The open-ended responses were manually reviewed.

The difficult complications were easy to define thanks to a precise description of the course of events and the patient’s use of specific terms. All serious complications (ureteral damage, deep thrombosis/embolism, sepsis and wound rupture) that were reported at the follow-up appointment had also been reported by the patient in the questionnaire. Another 17 were identified in the questionnaires. A review of medical records was conducted. Six cases were identified in records from the clinics, six were in other records (the patient indicated where they received treatment, and the operating clinic was unaware of the complication). Five could not be verified in medical records, there was no information about where treatment was received and the patients were not contacted separately.

Validation when automatically formulating text

In both the pre- and post-operative questionnaires and in all the physician forms, the recorded responses can be converted into automatically formulated text that can be used for medical records. Contact with the clinics following the use of automatically formulated text from the questionnaires revealed that approximately half of the attending physicians used the preoperative text suggestions when preparing for the operation. The perception at the preoperative assessment was that the text produced matched the anamnesis. Specially stated diseases and current pharmacological treatments in the preoperative questionnaire matched better than those noted in the medical record.

The automatically formulated text is in itself a validation that the answers filled in by the caregiver are accurate.

Assessments and decisions based on analyses (winter 2000)

Patients are very highly motivated to answer questionnaires integrated into their medical care. Using the system with mailings coordinated by the software with a personalised questionnaire that only contains patient-relevant questions has a very high response rate. Questionnaires are answered in full at a high frequency.

The identified difficulties in answering the questionnaires were, above all, that the patients did not understand the names of operations and diseases or remember the years in which the diseases or operations occurred. Previous validations had revealed that the meaning of various diseases and operations are often unknown to patients who do not have those diseases or who have not had those operations. Grading the distress patients reported is difficult when the degree of complaint varies. There were very few reported difficulties in understanding and answering the questions.

The questionnaires were deemed to have good validity as there were few critical opinions from medical care staff regarding the veracity of the questionnaire responses.

At a user meeting in the spring of 2000, participants expressed doubts about the reliability of the questionnaires. It was decided to continue with the extensive physician forms preoperatively and at the follow-up appointment until enough patients had been treated for a comparison of information given by patients and by physicians.

Patient descriptions of their post-operative complaints and complications are very accurate. Patients appear to be keen to report what happened postoperatively. Unfortunately, the data cannot be processed statistically since the options were too few and were not on a scale. Text analysis would be needed to create adequate answer alternatives based on patient descriptions, but this would require more cases.

Testing with patients showed that asking patients about problems postoperatively without using the word “complication” or its synonyms (except for “unexpected distress”) did not pass testing with patients. However, it is possible to differentiate between patient- and physician-reported complications. The high response rate of the postoperative questionnaires raised the question of whether they can replace routine follow-up appointments and how patients would perceive this. It was decided to implement one question about this in the questionnaire immediately.

When the word “complication” is used based on patient-reported complaints, many in the profession find it difficult to accept that patients can assess this. Instead, this is considered the task of the physician. This opinion continues to prevail in 2024.

Questionnaire development

Patient-reported post-operative complications

A 1999 physicians meeting revealed patients reported serious complications, such as ureteral damage or deep vein thrombosis, far too often when only mild problems had occurred. An analysis of the database verified this. Ureteral damage during hysterectomy amounted to 6% and deep vein thrombosis to 8%. In the complication classification created based on the descriptions in the open-ended responses, only the more serious cases were included as predefined options. In open-ended questions, patients were asked to describe anything else that might be of interest to the attending physician. When reviewing the serious complications reported by patients from a medical perspective, the open-ended responses often stated that it was a milder complication, but none of the answer alternatives allowed for this.

The 14 patients who marked these serious complications, where there was either a medical record at the clinic or an explanatory open-ended response, were contacted. Three had had the specified complication, while 11 marked it because it was the closest they could find among existing alternatives. For example, urethritis complaints were marked as ureteral damage. The conclusion was that the fixed answer alternatives had to be greatly expanded to include all commonly occurring complaints, so that respondents would have suitable answer alternatives. This left a total of 1,138 written descriptions of complications from patients. These were categorised and grouped using a qualitative method to create a classification catalogue useful for patients. For the various thematic complication categories (bleeding, infections, etc.), the option “None of the above” was added in 2000. This enabled obtaining complete answers for all themes. The catalogue and the revised questionnaires were then validated against patients at six locations in the country by the Educational Measurements Unit at Umeå University.

Preoperative information

The user meeting in the late autumn of 2001 had representatives from almost all participating clinics. The meeting decided to shorten the medical history form and remove the variables in the preoperative patient questionnaire before the operation. Both the physician questionnaire and the preoperative questionnaire had a complete battery of questions regarding medical history, i.e. symptoms, previous illnesses, serious allergies etc. Since the preoperative questionnaire was used as a basis for the operation at most participating hospitals, experience showed that the questionnaires gave a true picture of the patient’s medical history, which was verified before the operation. Comparisons between the physician-reported preoperative conditions corresponded very well with the responses from the questionnaire.

The preoperative answers given by patients were judged to have such validity that duplicating the questions was unnecessary. This was re-verified later in a 2017–2018 prolapse study. Questions about previous surgery in the preoperative questionnaire asked patients if they have previously had a prolapse operation. The pre-operative physician questionnaire asks if any prolapse surgery has been performed and, if so, what type. There is a very high degree of agreement between the medical records and patient information about previous prolapse surgery.

Questionnaire instead of a follow-up appointment

The post-operative questionnaire, which was previously sent out 6 weeks after surgery, added the question “Have you been called or will you be called to a follow-up appointment/examination because of the operation?”, with the answer options “Yes”, “No” and “Don’t know”. When answering “No” or “Don’t know”, patients received a follow-up question as to whether they wanted the clinic to contact them. The answer alternatives for that question were “No, I will contact you if there are any problems” or “Yes, I would like to be contacted” or “Yes, I would like a follow-up appointment”.

The gynecological section of the 2001 Swedish Medical Society meeting discussed possibly replacing routine follow-up appointments with a postoperative questionnaire. This would save money and increase the response frequency and thus the reliability of the register by eliminating missed routine follow-up appointments. Some of the audience considered this a very bad alternative that would impact the quality of the provided health care and that would simply be a cost-savings measure. An analysis of more than 2,000 post-operative questionnaire responses (after hysterectomy) to the follow-up appointment question revealed that 78% chose the alternative “No follow-up appointment wanted”, 12% the alternative “Yes, I would like to be contacted” (12%) and 10% the alternative “Yes, I would like a follow-up appointment”. These findings led to ending routine follow-up appointments. The question was divided into three parts to specifically ascertain whether the patient wanted the follow-up appointment or wanted to be contacted. It has since been changed into a two-part question with “I don’t need to be contacted” or “I would like to be contacted”, with an open-ended response field where the patient can describe why they want to be contacted.

The timing of the postoperative questionnaire has been moved to 8 weeks after surgery so that the initial healing process and potential complications can be identified and addressed.

The health declaration - the anaesthesia questionnaire (2004–2006)

The preoperative questionnaire had included an anaesthetic health declaration that was based on the existing checklist for anaesthesia assessment at Umeå University Hospital (NUS). The Anaesthesia Clinic had begun using the existing GynOp preoperative questionnaire before all gynecological operations. The clinic judged it to be so reliably answered by patients that they wanted to use it for general anaesthesia assessment. The questions concerning gynecological health were extracted from GynOp’s preoperative questionnaire.

The Anaesthesia Clinic at NUS sent the questionnaire to all anaesthesia clinics in the country requesting any additions needed to make it valid nationally. The question bank was also assessed by the Swedish Anaesthesiology Association. After modifications, the questions about understanding were validated by the Educational Measurements Unit at Umeå University on behalf of the Anaesthesia Clinic. They were then included in GynOp’s preoperative questionnaire. GynOp’s software was modified to allow the questionnaires to be processed and printed based on age and gender, regardless of clinic.

After the web-based questionnaire was launched, the majority of the operating clinics in Västerbotten used the existing preoperative questionnaire in GynOp prior to surgery. The questionnaire was used to select which patients need a preoperative anaesthesiologic assessment and which patients can go directly to surgery. By 2006, more than 50,000 patients had answered the questionnaire before gynecological or other operations in Västerbotten. The Anaesthesia Clinic has not reported any systematic errors or weaknesses in patient responses. The preoperative questionnaire is assessed by the anaesthesiologists as completely reliable in practical use, that is to say, it is valid.

Validating questionnaires when introducing GynOp sub-registers for incontinence, prolapse or tumours 2005–2006.

Until 2005, GynOp had consisted of the sub-registries for hysterectomy, adnexal and endometrial ablations/intrauterine surgery. From 2003 to 2005, intensive discussions were held with the Working Group for Urogynecology (UR-Arg) within the specialist association SFOG regarding quality registration of urogenital surgery[2].

Incontinence

Since 1998, Sigurd Kulseng-Hansen had run a surgical incontinence register in Norway, then called NUGG (from 2018 known as the Norwegian Female Incontinence Registry (NKIR)). NUGG had developed a set of validated incontinence questions. Ur-Arg wanted to include these questions and drew up an agreement with Kulseng-Hansen so that they could be incorporated into GynOp. The only validation deemed necessary was purely linguistic, and after translation the questionnaire was validated with patients.

Prolapse

Gunilla Tegerstedt's 2004 thesis *Clinical and epidemiological aspects of pelvic floor dysfunction* [2] studied and validated a number of questionnaire questions regarding symptoms and problems with prolapse. These questions were included in the prolapse questionnaire. A smaller validation for understanding was also conducted.

Validating online questionnaires at introduction (2007)

Starting in 2007, online questionnaires began to be used. Processing paper questionnaires (sending, receiving and registering the questionnaire responses) was time-consuming for administrators/medical secretaries at the clinics. Each paper questionnaire was estimated to cost a clinic around SEK 150, including time. With around 90,000 questionnaires used annually, this added up to significant costs.

Having online questionnaires and automating their mailing would consequently greatly reduce the work of participating clinics. Automated mailing would also eliminate problems in how participating clinics processed the questionnaires.

The first step was a literature review of whether the media used to respond to questionnaires could be expected to influence response content. A number of publications were found but none stated differences in response content related to the medium. Electronic media showed a higher percentage of complete answers since missing information can be flagged and a response required.

The design unit at the Educational Measurements Unit was tasked with designing the interface of the online questionnaires and converting the paper questionnaire to digital format. Adding the "None of the above" response alternative was very valuable when creating notifications of unanswered questions. The unit also validated that the responses provided in the electronic or paper formats were comparable.

[2] Prolapse and incontinence surgery.

Adding validated symptom-specific questions for pelvic floor distress (2021)

In recent years, the international organisations for pelvic floor distress and pelvic floor surgery (ICS and IUGA) have published compilations and recommendations for the highest ranked symptom-specific questions for evaluating complaints before and after reconstructive pelvic floor surgery. The highest ranked are internationally recognised and recommended by referees who review research based on register data. In 2021, GynOp's steering committee decided to replace existing pelvic floor questions with the following validated questions:

- PFDI-20 (Pelvic Floor Distress Inventory): 20 questions about prolapse, urinary and bowel symptoms [3].
- PGI-I (Patient Global Impression of Improvement): the patient's global satisfaction with the result of the operation [4, 5].
- Wexner score: validated questionnaire for mapping anal incontinence [6].
- KAPTAIN questionnaire: the first and only validated questionnaire for mapping symptoms related to defect-healed perineal body (the reference will be added when the study is published).

Regular validation of the questionnaire questions in GynOp

The pre- and postoperative questionnaires are answered annually by approximately 30,000 patients. Only 6% of the patients in total now indicate that they have had problems with one or some questions. The questionnaire responses are converted to text in sentence form that the majority of attending doctors read and then also react to if there are errors in either the text and the responses. After the first few years in the early 2000s, there have been very few complaints that the patients are unable to answer questions adequately. When introducing new questions, patients can complain that they have difficulty understanding or responding, whereby the questions are adjusted.

A structural difference between the patients' responses versus the doctors' is the assessment of the seriousness of a complication (unexpected distress). Patients often assess the severity as greater than doctors, but patients and doctors have different bases for their assessment. The patient assesses based on the distress and inconvenience experienced related to the information received regarding the postoperative course. Doctors assess based on the danger to organs and health caused by the complication. A painful postoperative urethritis with frequent obstructions can be perceived as extremely serious by a patient undergoing abdominal surgery but not by a doctor. A post-operatively discovered and repaired ureteral injury is assessed as serious by doctors but need not have been particularly troublesome for the patient who reports it as mild.

Additionally, it naturally occurs that patients can give different answers to the attending physician than provided in the questionnaire. Naturally, a patient can change their mind, but the question asked at the consultation may also be worded differently.

DUKS visits at participating clinics (2009–2018)

From 2009 to 2018, 19 DUKS visits were conducted at 19 clinics. DUKS is the acronym for the Swedish expression “datauttag och kvalitetssäkring”, which means data extraction and quality assurance and was the name of a training course offered to participating clinics.

The course took the following form: A DUKS involved a two-day visit by a sub-register manager and a representative from the GynOp office to a clinic, where half of day 1 was devoted to a review of the clinic’s organisation and routines related to the register, and where the GynOp office gave a presentation of a non-response analysis of sent/answered questionnaires and completed physician forms.

Prior to the visit, the clinic was tasked with conducting a review of a highly productive surgery period and the summer period from midsummer to the end of August to confirm that all surgeries performed during these two periods were included and registered in GynOp and to determine the reason for any non-reported surgeries. The clinic was also tasked with confirming that the patients reported to Landstingens Ömsesidiga Försäkringsbolag (LÖF), whose procedures were to be included in GynOp, had the corresponding complication registered in the quality register.

This data quality review was a prerequisite for the data extraction training that was then held on day 2. With the help of the briefing on day 1, we knew what was required to obtain valid data on day 2.

In most of the clinics that were visited, patient non-response was low, but there were some clinics that needed to improve their procedures for including all patients. The same applied to registered questionnaires.

Specific validation projects

Validation of postoperative antibiotic treatment (2014)

A 2014 validation study tested the validity of the GynOp register’s postoperative 8-week questionnaire regarding patient-reported infections with or without antibiotic treatment. The frequency of postoperative infections was also investigated. Read the full report in Swedish at https://www.gynop.se/for-kliniker/ovriga-rapporter/

Method

Data from the GynOp register were analysed. Patients in selected counties who reported infection and antibiotic treatment after surgery (group IwA) were compared with patient records to see whether they had received antibiotics prescribed by a doctor. The patients who reported infection after surgery without antibiotic treatment were also compared with medical records in a separate group (group InA). In the event of a discrepancy between questionnaire responses and patient records, a semi-structured telephone interview was conducted to clarify whether antibiotics had been taken.

Results

Of 216 patients in group IwA, documented medical records indicated that 192 had received antibiotics prescribed by a doctor. After telephone interviews, it was assessed that a further 16 patients had received antibiotics, even though this did not appear in the medical record. Telephone interviews were not held with three patients.

Of a total of 213 (100%) controlled patients in IwA, 208 (98%) had been treated with antibiotics, validating reported infections with antibiotic treatment ≥ 90%.

Group InA consisted of 151 patients, of which the medical records of 118 patients matched the questionnaire responses. After telephone interviews, it was assessed that one more patient had not been treated with antibiotics. Telephone interviews were not held with 11 patients. Of a total of 140 (100%) checked patients, it was assessed that 119 (85%) did not receive antibiotics. The patient material in group InA was too small to be able to validate the questionnaire regarding infection without antibiotic treatment.

Discussion

The postoperative infection frequency after undergoing hysterectomy is generally comparable between the country's hospitals, though individual hospitals can have a slightly higher frequency. No difference has been demonstrated regarding the frequency of infection after undergoing adnexal, incontinence or prolapse surgery. Data have indicated that there is some under-reporting of antibiotic use after surgery, which is why the infection rate in absolute numbers can be somewhat misleadingly low. However, no major difference has been demonstrated when comparing hospitals, which could indicate that the frequency of infection in gynecological operations is comparable in the country.

Conclusion

This study validates the reliability of the patient questionnaire for reported infection with antibiotic treatment. The patient material in group InA was too small to enable validation of the questionnaire regarding infection without antibiotic treatment.

As a direct consequence of this study, the questionnaire design of the 8-week questionnaire was changed to require a more active affirmative or negative response about antibiotic treatment in case of patient-reported postoperative infection.

Controls have shown that patient-reported prescribed medication course in questionnaires are more accurate than those reported in medical records. Prescribed medication courses indicated in medical records may be out of date, the patient may not take it as prescribed, or the medication was prescribed and recorded in another medical record system. The questionnaire is more reliable than medical records for whether the patient received antibiotic treatment in case of postoperative infection.

Based on their extensive clinical use and consequently their confirmation, the questionnaires included in GynOp are judged as valid with high reliability.

Validating the parity variable (2021)

In 2020, Larsudd-Kåverud et al. conducted a register study based on data from the GynOp register that included women older than 45 years who underwent surgery for prolapse or urinary incontinence during the period 2010–2016 [7]. A total of 52,000 women met the inclusion criteria. Within the framework of the study, a validation of GynOp's parity variable (number of births) was performed. The research group compared GynOp data against source data, i.e. information from Statistics Sweden (SCB). The result showed agreement in 94.7% of cases (5.7% lacked data). A total of 2% report "too few" children compared to what is registered in Statistics Sweden.

Validation of demographic and perioperative data (2021)

In 2022, Malin Brunes et al. published a study in which they compared the results of different surgical methods for apical prolapse [8]. Data in the study were obtained from the GynOp register, but to minimise the percentage of non-responses, a supplementary review of 454 patient records was conducted. These patients had undergone laparoscopic (n=297) or robot-assisted (n=157) prolapse surgery. In the review, a number of demographic and perioperative variables were

validated through comparison between GynOp data against source data (medical records). Patients were operated on in both public and private hospitals: Sahlgrenska University Hospital, Södersjukhuset, Danderyd Hospital, and Sophiahemmet. The results from the validation are shown in Table 1. In summary, the review showed a generally high agreement between GynOp and source data (85–98%).

Table 1. Validation of variables in GynOp via medical record comparison for laparoscopic and robot-assisted prolapse surgery.

Variable	Percentage with the same value stated in medical records and GynOp	Number of patients where information was available both in the medical record and in GynOp
BMI ±1	88%	147
Smoking (yes/no)	98%	96
Number of deliveries (0, 1–2 or >2)	98%	148
ASA classification (1–2 or 3–4)	96%	383
Previous prolapse surgery	89%	363
Perioperative bleeding ±25ml	88%	267
Operation time ±10 minutes	85%	362
Perioperative complication	98%	390

BMI = body mass index, ASA = American Society of Anesthesiologists Physical Status Classification

Analyses of measurement data

Study of missing data on suture materials in prolapse surgery

Ida Bergman et al. conducted an analysis of missing data in their study on suture materials in connection with prolapse surgery. They examined whether there were differences in demographic variables, such as age, BMI, parity, smoking, postmenopausal status, ASA classification and prolapse stage, between patients who had responded to the 1-year questionnaire compared to those who had not. The analysis showed no significant differences between the groups.[9]

Analysis of completion rate for a number of key variables

The results were presented per year for the years 2017–2021 (the year the patient underwent surgery) and divided by type of surgery. For 2017, operations performed between 1 July 2017 and 31 December 2017 are included because the merger of GynOp and Gyn-KvalitetsRegistret (GKR) was completed in June 2017. For variables from the 1-year questionnaire, values for 2021 are not yet available as patients will answer the questionnaire in 2024. The data material was retrieved from GynOp on 9 March 2022. The tables were compiled in the spring 2022.

The selection per operation type was done in the same way as in GynOp's annual reports and the interactive report.

For adnexal surgery, the selection is adnexal operations performed on a benign indication without simultaneous hysterectomy, incontinence surgery or reconstructive pelvic floor surgery. Operations with hysteroscopy indicated as primary incision are excluded.

For ruptures, the selection is perineal rupture grade 2, 3 or 4.

For hysterectomy, the selection is benign total or subtotal hysterectomies performed without concomitant pelvic floor reconstructive surgery. Operations with hysteroscopy indicated as primary incision are excluded.

For intrauterine surgery, the selection is hysteroscopic surgery.

For incontinence, the selection is incontinence operations performed without concomitant pelvic floor reconstructive surgery.

For reconstruction pelvic surgery, the selection is operations performed without concomitant incontinence surgery. Operations indicating vulva or hysteroscopy as primary incision are excluded.

Adnexa

	2017	2018	2019	2020	2021	2022	2023
Length, cm	76.5%	80.6%	82.3%	80.8%	80.1%	79.9%	79.6%
Weight, kg	76.1%	80.3%	81.9%	80.4%	79.8%	79.6%	79.1%
BMI	76.1%	80.3%	81.8%	80.3%	79.8%	79.6%	79.4%
ASA classification	100%	99.9%	100%	100%	100%	100%	100%
Planned/emergency surgery	98.4%	98.4%	98.9%	99.0%	99.0%	99.0%	98.8%
Operation time, min	99.9%	99.8%	99.8%	99.9%	99.9%	100%	100%
Perioperative bleeding, ml	100%	99.8%	99.8%	99.9%	99.9%	100%	100%
Primary incision	100%	100%	100%	100%	100%	100%	100%
PAD response shows (where PAD is sent)	93.4%	92.7%	94.4%	95.7%	93.9%	93.5%	91.5%
Date of discharge	96.8%	97.1%	97.9%	98.3%	97.7%	96.9%	90,1%
Anamnesis/operation/discharge listed	97.0%	97.3%	98.0%	98.5%	97.9%	98.2%	97.1%
Responses are registered in the 8-week questionnaire	76.8%	76.4%	78.8%	81.6%	79.9%	77.4%	76.9%
Patient-reported complication 8 weeks	75.9%	75.4%	77.5%	80.6%	78.6%	75.9%	75.0%
Responses registered in the 1-year questionnaire	68.3%	67.1%	72.7%	73.5%	68.7%	68.7%	
Patient-reported complication 1 year	67.5%	66.3%	72.0%	72.6%	67.9%	67.8%	
Patient-reported satisfaction 1 year	67.2%	65.9%	69.4%	69.2%	66.4%	66.7%	

Ruptures

	2017	2018	2019	2020	2021	2022	2023
Operation time, min	98.4%	98.6%	94.2%	93.5%	94.6%	93.6%	92.9%
Length, cm	96.9%	97.2%	91.8%	91.0%	92.6%	91.3%	92.5%
Weight, kg	95.5%	96.1%	91.1%	91.0%	92.6%	91.2%	92.1%
BMI	95.3%	95.6%	90.7%	90.7%	92.3%	90.8%	91.8%
Date of birth	99.4%	99.8%	94.9%	93.9%	95.0%	95.7%	96.4%
Assessment of the internal sphincter	43.6%	81,1%	95.2%	96.3%	93.1%	87.0%	87.0%
Responses registered in the 8-week questionnaire	72.7%	76.5%	74.2%	78.9%	69.9%	69.6%	63.9%
Patient-reported complication 8 weeks	70.9%	75.3%	73.0%	77.6%	68.4%	67.6%	61.7%
Responses registered in the 1-year questionnaire	65.2%	63.2%	71.4%	71.2%	62.1%	62.5%	
Patient-reported complication 1 year	64.4%	62.3%	70.2%	69.4%	60.8%	61.1%	
Patient-reported satisfaction 1 year	64.0%	61.9%	66.9%	66.6%	59.8%	60.1%	
Difficult to retain gas/faeces 1 year	64.3%	63.0%	70.6%	69.8%	61.2%	61.5%	

Hysterectomy

	2017	2018	2019	2020	2021	2022	2023
Length, cm	86.3%	88.6%	89.1%	88.1%	88.4%	88.0%	89.3%
Weight, kg	85.3%	88.1%	88.6%	87.6%	88.1%	87.8%	89.0%
BMI	85.3%	88.0%	88.5%	87.5%	88.1%	87.7%	89.0%
ASA classification	100%	100%	100%	100%	100%	100%	100%
Operation time, min	100%	99.9%	100%	99.9%	100%	99.9%	100%
Perioperative bleeding, ml	99.9%	100%	100%	99.9%	100%	100%	100%
Primary incision	100%	100%	100%	100%	100%	100%	100%
Uterus weight, grams	88.6%	87.8%	87.9%	85.4%	85.6%	84.1%	83.7%
Antibiotic prophylaxis perioperatively	100%	100%	100%	100%	100%	100%	100%
Date of discharge	97.6%	97.6%	98.3%	98%	97.4%	98%	97.3%
Anamnesis/operation/discharge listed	97.9%	97.9%	98.5%	98.2%	98%	98.3%	97.8%
Responses registered in the 8-week questionnaire	85.2%	83.9%	85.2%	89%	85.7%	84.5%	83.6%
Patient-reported complication 8 weeks	84.2%	83%	84%	87.9%	84.5%	83.5%	81.9%
Responses registered in the 1-year questionnaire	78.2%	77.8%	80.3%	82%	77.9%	78.3%	
Patient-reported satisfaction 1 year	77.2%	76.6%	76.3%	78.2%	75.8%	76.2%	

Incontinence

	2017	2018	2019	2020	2021	2022	2023
Length, cm	83.5%	88.8%	89.4%	86.5%	85.7%	87.2%	86.2%
Weight, kg	82.9%	88.6%	89.3%	86.3%	85.5%	87.1%	86.0%
BMI	82.9%	88.5%	89.2%	86.2%	85.5%	87.0%	85.9%
ASA classification	99.1%	99.0%	98.7%	99.6%	99.1%	99.4%	98.3%
Operation time, min	99.9%	100%	99.9%	100%	100%	99.9%	100%
Perioperative bleeding, ml	99.9%	100%	100%	100%	100%	100%	100%
Antibiotic prophylaxis perioperatively	100%	100%	100%	100%	100%	100%	100%
Date of discharge	97.3%	97.5%	97.1%	98.2%	97.7%	97.2%	96.9%
Responses registered in the 8-week questionnaire	84.7%	87.7%	87.6%	88.5%	84.6%	84.6%	82.6%
Patient-reported complications 8 weeks	83.9%	86.4%	86.4%	87.1%	83.1%	83.0%	81.0%
Questionnaire assessed 8 weeks (where responses are available)	91.0%	91.8%	92.6%	93.7%	91.1%	90.4%	83.8%
Responses registered in the 1-year questionnaire	79.4%	76.5%	78.4%	77.6%	70.5%	73.3%	
Patient-reported satisfaction 1 year	78.2%	75.6%	77.3%	76.4%	69.4%	72.6%	

Intrauterine surgery

	2017	2018	2019	2020	2021	2022	2023
Length, cm	58.1%	83.9%	82.2%	79.9%	79.6%	82.4%	82.3%
Weight, kg	57.8%	83.6%	81.8%	79.7%	79.4%	82.2%	82.0%
BMI	57.7%	83.4%	81.6%	79.6%	79.3%	82.1%	82.0%
ASA classification	93.7%	94.9%	95.0%	96.2%	95.9%	97.5%	96.1%
Operation time, min	98.5%	99.7%	99.8%	99.9%	99.9%	99.9%	99.9%
Perioperative bleeding, ml	74.6%	99.8%	99.8%	99.9%	99.9%	99.9%	99.9%
Perioperative complication	98.5%	99.8%	99.8%	99.9%	99.9%	99.9%	99.9%
Operating instrument	74.8%	99.7%	99.8%	99.9%	99.8%	99.9%	99.9%
Anaesthesia method	98.0%	100%	100%	100%	100%	100%	100%
PAD response shows (where PAD is sent)	66.8%	91.3%	89.0%	92.8%	90.4%	91.1%	89.1%
Date of discharge	95.5%	96.9%	96.6%	97.5%	97.0%	97.1%	96.2%
Responses registered in the 8-week questionnaire	63.9%	76.4%	74.7%	79.0%	74.2%	73.3%	71.7%
Days to normal ADL	61.0%	73.7%	71.8%	76.3%	71.8%	70.7%	69.3%
Patient's condition 8 weeks	67.5%	80.6%	79.1%	83.1%	79.1%	78.7%	76.7%
Responses registered in the 1-year questionnaire	60.8%	59.5%	61.8%	63.7%	58.1%	60.4%	

Reconstructive pelvic floor surgery

	2017	2018	2019	2020	2021	2022	2023
Length, cm	83.6%	89.8%	90.3%	89.7%	88%	89%	88.7%
Weight, kg	83.2%	89.4%	90.2%	89.4%	87.7%	88.8%	88.5%
BMI	82.8%	89.1%	89.9%	89.2%	87.5%	88.6%	88.3%
ASA classification	98.1%	98.6%	98.3%	98.7%	99.0%	98.6%	97.6%
Operation time, min	99.9%	99.9%	99.9%	100%	100%	100%	100%
Perioperative bleeding, ml	99.9%	99.9%	100%	100%	100%	100%	100%
Primary/recurrent surgery, in the same or new compartment	94.2%	95.0%	94.7%	95.0%	95.8%	95.1%	93.0%
Preoperative prolapse stage	89.4%	90.2%	88.5%	88.8%	89.1%	88.2%	88.2%
Date of discharge	96.1%	96.0%	96.4%	97.6%	97.2%	96.6%	96.1%
Responses registered in the 8-week questionnaire	87.3%	88.7%	87.5%	90.3%	86.6%	86.3%	85.4%
Patient-reported complication 8 weeks	85.4%	87.3%	86.4%	88.6%	84.9%	84.3%	83.3%
Postoperative infection up to and including 8 weeks	82.1%	90.2%	89.4%	92.7%	89.7%	89.0%	88.1%
Responses registered in the 1-year questionnaire	80.1%	79.6%	80.7%	82.7%	76.9%	78.6%	
Patient-reported satisfaction 1 year	78.3%	77.8%	77.4%	78.1%	74.1%	75.3%	
Patient-reported prolapse symptom 1 year	78.3%	77.7%	79.3%	81.6%	75.5%	77.6%	
Patient-reported complication 1 year	78.7%	78.2%	79.4%	81.1%	75.6%	77.3%	

Ongoing validation

The GYNCOM project: validation of complications in GynOp's sub-registers for hysterectomy, adnexal and pelvic reconstructive surgery

Purpose

Study complications registration in the sub-registers for hysterectomy, adnexal and pelvic reconstructive surgery in GynOp for reproducibility, feasibility and reliability

Background

Complications after gynecological surgery in Sweden are registered according to type and severity and according to Clavien-Dindo. Clavien-Dindo is validated for general surgery and urology but not for gynecological surgery.

Study 1

National online questionnaire study for gynecological clinics in Sweden consisting of fictitious patient cases with uterus/adnexal surgery, to evaluate and validate the assessment of postoperative complications in the GynOp register [10].

Study 2

Comparison of complication registration after uterus/adnexal surgery in GynOp with registered complication diagnoses in the National Patient Register, registered death in the National Cause of Death Register and antibiotic prescription in the National Prescribed Drug Register.

Study 3

National online questionnaire study for gynecological clinics in Sweden consisting of fictitious patient cases with reconstructive pelvic surgery, to evaluate and validate the assessment of postoperative complications in the GynOp register [10].

Study 4

Comparison of complication registration after reconstructive pelvic surgery in GynOp with registered complication diagnoses in the National Patient Register, registered death in the National Cause of Death Register and antibiotic prescriptions in the National Prescribed Drug Register.

Validation of register data against data in medical records systems

Data from GynOp is used for quality review at participating clinics throughout Sweden and for research. This makes it of the utmost importance to know whether the information reported in GynOp's physician forms and questionnaires is correct. To find out the veracity/validity of various variables, a comparison is needed with data in GynOp against source data, for example the clinics' medical record systems.

Validation is performed as quality assurance within the specialist training for obstetricians/gynaecologists. The doctor in specialist training performing the validation receives an Excel file with 150 randomly selected patients, including their personal identity number/reserve number and operation date (25 patients for each sub-register). The doctor also receives clear instructions about the variables to ensure that all reviewers fill in the same information. The doctor searches for correct source data information in, for example, the medical record and/or in the operation planning tool and fills in the empty fields in the Excel file. The completed Excel file is sent back to GynOp's office, which in turn sends another Excel file containing the information that is registered, so that the clinic can perform its own comparison between the source data and the register data. All files are sent via encrypted email.

The plan is for at least 10 validations to be performed at different clinics. Then these will be compiled and the report on the validation will be published on GynOp's website www.gynop.se and as a scientific article.

Variables that are validated divided per sub-register

Adnexal

- Operation time, min (O6aOptid)
- Discharge date (UuDatUtskriv)
- Perioperative bleeding, ml (O6aPerOpBlodningMl)
- ASA classification (AsASA)
- Length, cm (E14BMILangd)
- Weight, kg (E14BMIVikt)
- Planned/emergency surgery (AaPlanAkutAtgard)
- PAD response shows (PAD)

Ruptures

- Operation time, min (O6aOptid)
- Length, cm (OBrLangd)
- Weight, kg (OBrVikt)
- Degree of rupture (OBrPerinealruptGrad)
- Date of delivery (OBrPartusdatum)

Hysterectomy

- Operation time, min (O6aOptid)
- Discharge date (UuDatUtskriv)
- Perioperative bleeding, ml (O6aPerOpBlodningMl)
- ASA classification (AsASA)
- Length, cm (E14BMILangd)
- Weight, kg (E14BMIVikt)
- Uterus weight, grams (O3uUterusvikt)
- Antibiotic prophylaxis perioperatively (O6aABprof)

Intrauterine surgery

- Operation time, min (O6aOptid)
- Discharge date (UuDatUtskriv)
- Perioperative bleeding, ml (O6aPerOpBlodningMl)
- ASA classification (AsASA)
- Length, cm (E14BMILangd)
- Weight, kg (E14BMIVikt)
- Operating instrument (OpInstrument)

Incontinence – Mid urethral sling procedures

- Operation time, min (O6aOptid)
- Discharge date (UuDatUtskriv)
- Perioperative bleeding, ml (O6aPerOpBlodningMl)
- ASA classification (AsASA)
- Length, cm (E14BMILangd)
- Weight, kg (E14BMIVikt)
- Antibiotic prophylaxis perioperatively (O6aABprof)

Reconstructive pelvic floor surgery

- Operation time, min (O6aOptid)
- Discharge date (UuDatUtskriv)
- Perioperative bleeding, ml (O6aPerOpBlodningMl)
- ASA classification (AsASA)
- Length, cm (E14BMILangd)
- Weight, kg (E14BMIVikt)
- Primary/recurrent surgery, in the same or new compartment (PrimarRecidiv)
- Preoperative prolapse stage (StadiumFramvagg, StadiumBakvagg, StadiumCervixVagtopp)

For continuous variables, a certain margin of error is accepted to enable the variables to be considered to agree.

- Operation time +/- 10 minutes
- Perioperative bleeding +/- 50 ml
- Length +/- 3 cm
- Weight +/- 5 kg
- Uterus weight +/- 20 grams

To be continued. . .

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