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**Eidgenössische Qualitätskommission EQK**

# Projektschlussbericht Swissnoso/SIRIS zur Qualitätsverbesserung bei orthopädischen Implantatinfektionen

Merging Data from Swiss Implant Register (SIRIS) with surgical site infection database (Swissnoso) for quality improvement.

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# Content

# Summary

The monitoring of postoperative infections by Swissnoso in collaboration with the National Association for Quality Development (ANQ) is an established component of quality assurance in surgery. The scope of recording is at the discretion of the hospital, therefore Swissnoso receives a subset of all orthopedic surgeries. Despite vigorous quality checks including on-site checks, Swissnoso does not know in detail whether all infections and details of patients are included from the collective of all operations performed, nor the mortality after the surgery.

The SIRIS Hip and Knee Implant Register primarily serves to monitor the quality of treatment of surgical procedures related to implantations of hip and knee prosthesis and as an early warning system for the implants used. With the recording of the primary procedures as baseline, the registration of revisions and reoperations, including their reasons, is central to the calculation of the survival of implants. More than 97% of all hip and knee arthroplasty operations are registered in SIRIS, whereas only a selection is registered in Swissnoso. The focus of Swissnoso surveillance is to identify the incidence of Surgical Site Infections (SSI) including details of the infection and the responsible pathogen, while SIRIS does detect infections only if a revision surgery is performed. It has to be noted, that every implant associated infection always requires one or more reoperations or revisions for the treatment of an infection, combined with antibiotic therapy.

The aim of this project was to 1) link the two national registers Swissnoso and SIRIS in a coded form, thereby measuring the quality of data entry, 2) identify quality measures to prevent SSIs after implant surgery and, if successful, 3) provide a background for a project avoiding duplication of data entry and recording.

## Methods

A probabilistic record linkage method was applied to match records from one data set with high probability to a record of the second data set. Swissnoso has pseudo-anonymized data collection, so that traceability at individual patient level is only possible by the hospital collecting the data. With "written informed consent" of the patient, SIRIS has seamless proof of the identity of the individual patient.

## Results

1. Link the two national registers Swissnoso and SIRIS in a coded form, thereby measuring the quality of data entry

    1.1. *Estimation of the linkage quality*

    98.5% of the linked pairs had no alternative link. Among the linked pairs, the proportion of full match on the most important linkage variables was around 99%.

    1.2. *Results of the probabilistic record linkage Swissnoso – SIRIS*

    Overall, 178’325 out of 204’104 (87.4%) included Swissnoso cases were linked to a SIRIS case (hip 87.5%, knee 87.2%). The linkage without 2012 data (SIRIS started only in September 2012) leads to an overall linkage proportion of 91.9% (hip 92.4%, knee 91.3%).

    1.3. *Results of the probabilistic record linkage SIRIS-Swissnoso*

Overall, 178’325 out of 240’672 (74.1%) included SIRIS cases could be linked to a Swissnoso case (hip 77.4%, knee 70.0%).

1.4. *Agreement status of infection in SIRIS and in Swissnoso*

Swissnoso identified 1 688 infections in 160 521 patients (1.1%); SIRIS identified 881 infections (0.5%). Agreement of Swissnoso detected infections by SIRIS was 696/1688 (41%). The rate increased for the most relevant organ/space infections to 683/1149 (59%).

Agreement of SIRIS detected infections by Swissnoso was 696/881 (79%).

The main reasons for disagreement were: i) no very clear and objective definition of an infection in SIRIS, ii) Swissnoso missed cases due to lack of follow-up. This has become more important than in previous years as Swissnoso and ANQ accepted to shorten the follow-up from 1 year to 3 months, in order to provide up-to-date reporting and reduce workload.

2. *Identify quality measures to prevent postoperative surgical infections after implant surgery*

We identified a strong association between an organ/space surgical site infections after orthopedic implant surgery according to Swissnoso and an increased hazard in the 10-year mortality. The adjusted hazard ratio was 2.11 (1.76-2.54; ($p<0.001$). The hazard was evenly distributed throughout the (maximum) 10-year follow up. This decisive quality outcome shows how important it is to continue investing in the prevention for these infections. Potentially modifiable variables were not examined in this study.

3. *Providing the necessary background for Avoiding duplication of data entry and recording.*

A major step forward to avoid double-entry of data would be to rely on SIRIS data entry, transfer cases with infection-suspicion to the Swissnoso team to confirm or reject the case and complement the SIRIS dataset with data of microbiology and infection type by the local hospital. All patients must be currently entered in SIRIS AND Swissnoso databases despite only around 1% develop SSI. We estimated the time for healthcare personnel approximately 160 hours/100 patients, or approximately 5% FTE. Many working hours for recording the data could be saved and invested into infection prevention. Our project succeeded to provide sufficient background to set-up such a project to avoid double-entry, and ultimately rely on SIRIS data for surveillance of orthopedic SSIs.

## Conclusions

1. This merge provides proof of concept that such merges are feasible and add to the quality improvement to prevent SSIs in orthopedic surgery. This concept may be used as template for further linkages of databases.
2. The advantage of hosting both databases at the same location was a crucial advantage for the success.
3. The strong association of organ/space SSI (according to Swissnoso) with increased hazard for the 10-year mortality was a surprise. It underlines that prevention of SSIs not only significantly decrease morbidity, but also mortality, even years after surgery. It supports new actions to roll out the current activity to decrease SSIs after implant surgery, with focus on process parameters – for example *Staphylococcus aureus* decolonization prior surgery, timing of antimicrobial prophylaxis, and perioperative glucose control.

# Zusammenfassung

Das Monitoring postoperativer Infektionen durch Swissnoso in Zusammenarbeit mit dem Nationalen Verein für Qualitätsentwicklung in Spitälern und Kliniken (ANQ) ist fester Bestandteil der Qualitätssicherung in der Chirurgie. Der Umfang der Datenerfassung liegt jedoch im Ermessen des Spitals, so dass Swissnoso nur einen Teil der Daten zu allen orthopädischen Operationen erhält. Trotz strenger Qualitätskontrollen, auch vor Ort, weiss Swissnoso nicht im Detail, ob alle Infektionen und Patientendaten aus der Gesamtheit der durchgeführten Operationen erfasst werden. Ebenso wenig ist die genaue Mortalität nach den Eingriffen bekannt.

Das SIRIS-Hüft- und Knieimplantatregister dient in erster Linie der Qualitätsüberwachung bei chirurgischen Eingriffen zur Implantation von Hüft- und Knieprothesen und als Frühwarnsystem bei Versagen der eingesetzten Implantate. Neben der Erfassung der Primäreingriffe als Ausgangspunkt ist die Registrierung der Revisions- und Reoperationen, einschliesslich ihrer Gründe, zentral für die Berechnung der Implantatüberlebensrate. In SIRIS werden über 97 % aller Hüft- und Knieendoprothesenoperationen erfasst, in Swissnoso nur eine Auswahl. Der Schwerpunkt des Monitorings durch Swissnoso liegt auf der Ermittlung der Inzidenz von postoperativen Wundinfektionen (Surgical Site Infections, SSI), einschliesslich der Einzelheiten der Infektion und des verantwortlichen Erregers, während SIRIS Infektionen nur erfasst, wenn eine Revisionsoperation durchgeführt wird. Zu beachten ist, dass jede implantatassoziierte Infektion zur Behandlung immer eine oder mehrere Re- oder Revisionsoperationen in Kombination mit einer Antibiotikatherapie erfordert.

Ziel dieses Projekts war es, 1) die beiden nationalen Register Swissnoso und SIRIS in kodierter Form zu verknüpfen und dabei die Qualität der Dateneingabe zu messen, 2) Qualitätsmassnahmen zur SSI-Prävention nach Implantatoperationen zu identifizieren und bei Erfolg 3) eine Grundlage für ein Projekt zur Vermeidung von doppelten Dateneingaben und -erfassungen zu schaffen.

### Methoden

Es wurde eine probabilistische Datenverknüpfungsmethode angewandt, um die Daten des ersten Registers mit hoher Wahrscheinlichkeit mit denjenigen des zweiten abzugleichen. Swissnoso hat die Datenerfassung pseudonymisiert, so dass die Rückverfolgbarkeit auf individueller Patientenebene nur durch das datenerfassende Spital möglich ist. Mit der «schriftlichen und aufgeklärten Einwilligung» des Patienten oder der Patientin hat SIRIS einen eindeutigen Identitätsnachweis der einzelnen Person.

### Ergebnisse

*1.* Kodierte Verknüpfung der beiden nationalen Register Swissnoso und SIRIS mit Messung der Dateneingabe-Qualität

1.1. *Schätzung der Verknüpfungsqualität*

Bei 98,5 % der verknüpften Paare fand sich keine alternative Verknüpfungsmöglichkeit. Bei den verknüpften Paaren betrug der Anteil der vollständigen Übereinstimmung der wichtigsten Verknüpfungsvariablen rund 99 % .

1.2. *Ergebnisse der probabilistischen Datenverknüpfung Swissnoso–SIRIS*

Insgesamt wurden 178 325 der 204 104 einbezogenen Swissnoso-Fälle (87,4 %) mit einem SIRIS-Fall verknüpft (Hüfte 87,5 %, Knie 87,2 %). Die Verknüpfung ohne die Daten aus dem Jahr 2012 (SIRIS

wurde erst im September 2012 lanciert) führt zu einer Gesamtverknüpfungsquote von 91,9 % (Hüfte 92,4 %, Knie 91,3 %).

1.3. *Ergebnisse der probabilistischen Datenverknüpfung SIRIS–Swissnoso*

Insgesamt konnten 178 325 der 240 672 einbezogenen SIRIS-Fälle (74,1 %) mit einem Swissnoso-Fall verknüpft werden (Hüfte 77,4 %, Knie 70,0 %).

1.4. *Übereinstimmung Infektionsstatus in SIRIS und Swissnoso*

Swissnoso identifizierte bei 160 521 Patientinnen und Patienten 1688 Infektionen (1,1 %) und SIRIS 881 (0,5 %). Die Übereinstimmung der von Swissnoso ermittelten Infektionen mit denjenigen nach SIRIS betrug 696/1688 (41 %). Bei den wichtigsten Organ-/Rauminfektionen stieg die Rate auf 683/1149 (59 %).

Die Übereinstimmung der von SIRIS ermittelten Infektionen mit denjenigen nach Swissnoso betrug 696/881 (79 %).

Die Hauptgründe für Nichtübereinstimmungen waren: i) keine klare und objektive Definition einer Infektion in SIRIS, ii) Swissnoso verpasste Fälle aufgrund fehlender Nachverfolgung. Dieses Problem fiel aktuell stärker ins Gewicht als in den Vorjahren, da Swissnoso und der ANQ sich bereit erklärt haben, das Follow-up von einem Jahr auf drei Monate zu verkürzen, um eine aktuelle Berichterstattung zu gewährleisten und die Arbeitslast zu verringern.

2. *Ermittlung von Qualitätsmassnahmen zur SSI-Prävention nach Implantatoperationen*

Wir stellten einen starken Zusammenhang zwischen von Swissnoso erfassten Organ-/Rauminfektionen nach einer orthopädischen Implantatoperation und einem erhöhten 10-Jahres-Mortalitätsrisiko fest. Die bereinigte Hazard Ratio betrug 2,11 (1,76-2,54; (p<0,001). Das Risiko war über die gesamte (maximale) 10-jährige Nachbeobachtungszeit gleichmässig verteilt. Dieses entscheidende Qualitätsergebnis zeigt, wie wichtig es ist, weiterhin in die Prävention dieser Infektionen zu investieren. Potenziell modifizierbare Variablen wurden in dieser Studie nicht untersucht.

3. *Bereitstellung der erforderlichen Hintergrundinformationen zur Vermeidung doppelter Dateneingaben und -erfassungen*

Ein wichtiger Schritt zur Vermeidung doppelter Dateneingaben wäre, sich auf die SIRIS-Dateneingabe zu stützen, Fälle mit Infektionsverdacht an das Swissnoso-Team weiterzuleiten, um den Fall zu bestätigen oder abzulehnen, und den SIRIS-Datensatz mit Daten zu Mikrobiologie und Infektionstyp des örtlichen Spitals zu ergänzen. Alle Patientinnen und Patienten müssen derzeit in der SIRIS- und der Swissnoso-Datenbank erfasst werden, obwohl nur etwa 1 % SSI entwickelt. Wir schätzten den Zeitaufwand für das Gesundheitspersonal auf ca. 160 Stunden/100 Patient/-innen bzw. ca. 5% VZÄ. Viele Arbeitsstunden für die Datenerfassung könnten eingespart und in die Infektionsprävention investiert werden. Mit unserem Projekt ist es gelungen, genügend Hintergrundinformationen für die Umsetzung eines solchen Projekts zu liefern, um Doppelerfassungen zu vermeiden und sich letztlich auf die SIRIS-Daten zur Überwachung orthopädischer SSI zu stützen.

## Schlussfolgerungen

1. Diese Datenverknüpfung beweist, dass solche Verknüpfungen machbar sind und zur Qualitätsverbesserung bzw. zur Vermeidung von SSI in der orthopädischen Chirurgie beitragen. Das Konzept kann als Modell für weitere Datenverknüpfungen verwendet werden.
2. Das Hosting beider Datenbanken am selben Ort war ein entscheidender Erfolgsfaktor.
3. Der starke Zusammenhang zwischen Organ-/Raum-SSI (nach Swissnoso) und erhöhtem 10-Jahres-Mortalitätsrisiko war überraschend. Er zeigt auf, dass die SSI-Prävention nicht nur die Morbidität, sondern auch die Mortalität selbst Jahre nach der Operation signifikant verringert. Das spricht für neue Massnahmen zur umfassenderen Eindämmung von SSI nach Implantateingriffen, wobei der Schwerpunkt auf Prozessparametern liegt – zum Beispiel Dekolonisierung von *Staphylococcus aureus* vor der Operation, Zeitpunkt der antimikrobiellen Prophylaxe und perioperative Glukosekontrolle.

# Résumé

La surveillance des infections postopératoires, assurée en collaboration avec l'Association nationale pour le développement de la qualité dans les hôpitaux et les cliniques (ANQ), est une composante établie de l'assurance-qualité en chirurgie. Les hôpitaux définissant eux-mêmes l'étendue des données saisies, Swissnoso ne reçoit qu'une partie des données relatives aux interventions chirurgicales orthopédiques. Malgré des contrôles de qualité rigoureux incluant des visites sur place, Swissnoso ne sait donc pas si toutes les infections et si toutes les données des patients opérés ont été recensées et n'a pas connaissance du taux de mortalité postopératoire.

Le registre des implants SIRIS hanche et genou sert en premier lieu à surveiller la qualité du traitement des procédures chirurgicales liées à l'implantation de prothèses de la hanche et du genou, ainsi qu'à assurer une fonction d'alerte précoce pour les implants utilisés. Parallèlement à la saisie des interventions primaires comme base de référence, le recensement des révisions et des réopérations, ainsi que de leurs motifs, est essentiel pour calculer le taux de survie des implants. Si plus de 97 % des opérations d'arthroplastie de la hanche et du genou sont enregistrées dans SIRIS, seule une sélection est saisie dans Swissnoso. L'objectif premier de la surveillance assurée par Swissnoso est de recenser non seulement l'incidence des infections du site chirurgical (*Surgical Site Infections*, SSI), mais aussi les détails de l'infection et l'agent pathogène responsable. De son côté, SIRIS ne décèle les infections que si une reprise chirurgicale est effectuée. À noter que toute infection liée à un implant nécessite toujours une ou plusieurs réopérations ou révisions en association avec une antibiothérapie.

Ce projet poursuivait les objectifs suivants : 1) coupler les deux registres nationaux Swissnoso et SIRIS sous une forme codée afin d'évaluer la qualité de la saisie des données ; 2) identifier des mesures de qualité pour prévenir les SSI après une chirurgie avec implant et, si le projet se révélait concluant ; 3) jeter les bases d'un projet permettant d'éviter la saisie et l'enregistrement à double des données.

## Méthodologie

Une méthode probabiliste de couplage d'enregistrements a été utilisée pour mettre en relation, selon un niveau de probabilité élevé, des enregistrements relevant de deux ensembles de données distincts. Swissnoso a recours à des données pseudonymisées, de sorte que seul l'hôpital qui collecte les données peut effectuer des recoupements avec un patient. Le consentement éclairé écrit du patient fournit à SIRIS une preuve irréfutable de l'identité du patient.

## Résultats

1. *Coupler les deux registres nationaux Swissnoso et SIRIS sous une forme codée afin d'évaluer la qualité de la saisie des données*

    1.1. *Estimation de la qualité du couplage*

    Aucun couplage alternatif n'était proposé pour 98,5 % des paires constituées. Parmi les paires constituées, la proportion de concordance totale sur les variables de couplage les plus importantes était de 99 %.

1.2. *Résultats du couplage probabiliste d'enregistrements Swissnoso-SIRIS*

Au total, 178 325 (87,4 %) des 204 104 cas Swissnoso inclus ont été couplés avec un cas SIRIS (hanche : 87,5 % ; genou : 87,2 %). SIRIS ayant été mis en place en septembre 2012, le retrait des données datant de 2012 a permis d'atteindre un taux global de couplage de 91,9 % (hanche : 92,4 % ; genou : 91,3 %).

1.3. *Résultats du couplage probabiliste d'enregistrements SIRIS-Swissnoso*

Au total, 178 325 (74,1 %) des 240 672 cas SIRIS inclus ont pu être couplés avec un cas Swissnoso (hanche : 77,4 % ; genou : 70,0 %).

1.4. *Statut de concordance d'infections entre SIRIS et Swissnoso*

Swissnoso a recensé 1688 infections chez 160 521 patients (1,1 %) ; SIRIS en a relevé 881 (0,5 %). La concordance entre les infections recensées par Swissnoso et celles de SIRIS a été de 696 sur 1688 (41 %). Pour les infections d'organes ou de cavités les plus pertinentes, la concordance a été de 683 sur 1149 (59 %).

La concordance entre les infections recensées par SIRIS et celles de Swissnoso a été de 696 sur 881 (79 %).

Les principales causes de non-concordance étaient les suivantes : i) SIRIS n'a pas défini clairement et objectivement ce qu'est une infection ; ii) Swissnoso a manqué des cas en raison d'un suivi insuffisant, une problématique qui a encore gagné en importance depuis que Swissnoso et l'ANQ ont accepté de limiter le suivi à trois mois (au lieu d'un an) afin de réduire la charge de travail et d'être en mesure d'établir les rapports en temps voulu.

2. *Identifier des mesures de qualité pour prévenir les SSI après une chirurgie avec implant*

Nous avons identifié une forte corrélation entre les SSI d'organes ou de cavités après la pose d'un implant orthopédique (selon Swissnoso) et un risque accru de mortalité à dix ans. Le rapport de risque ajusté s'élevait à 2,11 (1,76-2,54 ; [p<0,001]). Le risque était réparti uniformément tout au long du suivi (maximum) de dix ans. Ce résultat qualitatif décisif montre l'importance de continuer à investir dans la prévention de ces infections. Les variables potentiellement modifiables n'ont pas été examinées dans cette étude.

3. *Jeter les bases d'un projet permettant d'éviter la saisie et l'enregistrement à double des données*

Pour éviter la double saisie des données, on pourrait envisager de prendre pour base les données saisies dans SIRIS, de transférer les cas de suspicion d'infection à l'équipe de Swissnoso pour les confirmer ou les rejeter, et de compléter la base de données SIRIS avec des données microbiologiques et relatives au type d'infection fournies par l'hôpital local. Actuellement, bien que seul 1 % des patients contracte une SSI, ils doivent tous être saisis dans les bases de données SIRIS ET Swissnoso. Nous avons estimé le temps nécessaire au personnel soignant à environ 160 heures/100 patients, ou environ 5% EPT. De nombreuses heures de travail pourraient donc être économisées et consacrées à la prévention des infections. Nos travaux fournissent des bases suffisamment solides pour mettre sur pied un projet destiné à éviter la saisie et l'enregistrement à double des données et, en fin de compte, permettre le recours aux données SIRIS pour la surveillance des SSI en chirurgie orthopédique.

## Conclusions

1. Ce couplage de bases de données démontre la faisabilité de ce type de démarches et les gains de qualité qu'elles apportent pour prévenir les SSI en chirurgie orthopédique. Ce concept peut servir de modèle à d'autres couplages de bases de données.
2. L'hébergement des deux bases de données au même endroit a constitué un avantage déterminant pour la réussite du projet.
3. La forte corrélation entre les SSI d'organes ou de cavités (d'après Swissnoso) et un risque accru de mortalité à dix ans a été une surprise. Cela montre que la prévention des SSI permet non seulement de réduire sensiblement la morbidité, mais aussi la mortalité, même des années après l'intervention chirurgicale. Il appelle de nouvelles mesures visant à déployer les actions actuelles de réduction des SSI après la pose d'implants, en mettant l'accent sur différents paramètres du processus, par exemple sur la décolonisation préopératoire de *Staphylococcus aureus*, sur la prophylaxie antibiotique ou sur le contrôle périopératoire de la glycémie.

# Riassunto

Il monitoraggio delle infezioni postoperatorie condotto da Swissnoso in collaborazione con l'Associazione nazionale per lo sviluppo della qualità in ospedali e cliniche (ANQ) è una componente riconosciuta della garanzia della qualità in chirurgia. Quanto viene effettivamente rilevato, è a discrezione dell'ospedale, per cui Swissnoso riceve solo una parte dei dati relativi a tutti gli interventi ortopedici. Malgrado rigorosi controlli di qualità comprendenti anche controlli *in situ*, Swissnoso non sa in dettaglio se in tale set di dati siano incluse tutte le informazioni relative ai pazienti e alle infezioni da questi contratte sull'insieme delle operazioni eseguite né quale sia la mortalità post-operatoria.

Il registro delle protesi SIRIS anca e ginocchio serve prioritariamente a monitorare la qualità del trattamento delle procedure chirurgiche legate agli impianti di protesi di anca e ginocchio e funge da sistema di allerta precoce in caso di malfunzionamento delle protesi utilizzate. Avendo come base di riferimento il rilevamento delle procedure primarie, la registrazione delle revisioni chirurgiche, dei reinterventi e delle relative ragioni è essenziale ai fini del calcolo della durata di vita delle protesi. Oltre il 97 % di tutte le operazioni artroplastiche di anca e ginocchio è registrato in SIRIS, mentre solo una selezione è registrata in Swissnoso. La sorveglianza di Swissnoso mira a identificare l'incidenza delle infezioni del sito chirurgico (surgical site infections, SSI), compresi i dettagli relativi all'infezione e il patogeno responsabile, mentre SIRIS rileva le infezioni soltanto se viene effettuato un intervento di revisione chirurgica. Va notato che il trattamento di un'infezione associata a una protesi richiede sempre uno o più reinterventi o revisioni chirurgiche combinati a una terapia antibiotica.

Scopo del presente progetto era: 1) abbinare i due registri nazionali Swissnoso e SIRIS in forma codificata per misurare la qualità della registrazione dei dati; 2) identificare misure di qualità per prevenire le SSI dopo interventi di chirurgia protesica; e, in caso di successo, 3) fornire i presupposti per realizzare un progetto finalizzato a evitare doppioni a livello di inserimento e rilevamento dei dati.

## Metodologia

Per abbinare le registrazioni del primo set di dati con quelle del secondo, secondo un livello di probabilità elevata, è stato applicato un metodo di «record linkage» probabilistico. Swissnoso ha pseudoanonimizzato la raccolta di dati, di modo che soltanto l'ospedale che raccoglie i dati possa tracciare un singolo paziente. Attraverso il «consenso informato scritto» del paziente, SIRIS ha invece una prova inconfutabile dell'identità del singolo paziente.

## Risultati

1. Abbinare i due registri nazionali Swissnoso e SIRIS in forma codificata per misurare la qualità della registrazione dei dati

    1.1. *Stima della qualità dell'abbinamento*

    Il 98,5 % delle coppie abbinate non presentava un abbinamento alternativo. Tra le coppie abbinate, la proporzione di corrispondenza esatta per le maggiori variabili di abbinamento era attorno al 99 %.

    1.2. *Risultati del record linkage probabilistico Swissnoso – SIRIS*

Nel complesso, 178 325 dei 204 104 (87,4 %) casi inclusi in Swissnoso erano abbinati a un caso SIRIS (anca 87,5 %, ginocchio 87,2 %). L'abbinamento senza i dati del 2012 (SIRIS è stato avviato solo nel settembre 2012) dà un tasso di abbinamento complessivo del 91,9 % (anca 92,4 %, ginocchio 91,3 %).

1.3. *Risultati del record linkage probabilistico SIRIS-Swissnoso*

Nel complesso, 178 325 dei 240 672 (74,1 %) dei casi inclusi in SIRIS hanno potuto essere abbinati a un caso Swissnoso (anca 77,4 %, ginocchio 70,0 %).

1.4. *Concordanza dello stato di infezione in SIRIS e Swissnoso*

Swissnoso ha identificato 1688 infezioni in 160 521 pazienti (1,1 %) contro le 881 infezioni (0,5 %) registrate da SIRIS. La concordanza delle infezioni rilevate da Swissnoso con quelle di SIRIS era di 696/1688 (41 %), mentre per le infezioni di organo/spazio più importanti il tasso saliva a 683/1149 (59 %).

La concordanza delle infezioni rilevate da SIRIS con quelle di Swissnoso era di 696/881 (79 %).

Le principali ragioni di discordanza erano: i) mancanza di definizione chiara e oggettiva di un'infezione in SIRIS, ii) mancata rilevazione di casi in Swissnoso per assenza di follow-up. Quest'ultimo problema si è aggravato rispetto agli anni precedenti a seguito della decisione di Swissnoso e ANQ di abbreviare il follow-up da 1 anno a 3 mesi per fornire rendicontazioni aggiornate e ridurre il carico di lavoro.

2. *Identificare misure di qualità per prevenire le SSI dopo interventi di chirurgia protesica*

È stata identificata una forte associazione tra le infezioni del sito chirurgico di un organo/spazio dopo un intervento di chirurgia protesica ortopedica (secondo Swissnoso) e un aumento del rischio nella mortalità a 10 anni. Il rapporto di rischio corretto era di 2,11 (1,76-2,54; ($p<0,001$). Il rischio era distribuito uniformemente sull'arco dei 10 anni (massimo) di follow-up. Questo risultato qualitativo decisivo dimostra quanto sia importante continuare a investire nella prevenzione di queste infezioni. Questo studio non ha preso in esame varianti potenzialmente modificabili.

3. *Fornire i presupposti per realizzare un progetto finalizzato a evitare doppioni a livello di inserimento e rilevamento dei dati*

Un importante passo avanti per evitare il doppio inserimento dei dati consisterebbe nell'affidarsi all'inserimento dei dati SIRIS, trasferire i casi di sospetta infezione al team di Swissnoso perché confermino o rifiutino il caso e integrare il set di dati SIRIS con i dati sulla microbiologia e sul tipo di infezione da parte dell'ospedale locale. Attualmente, tutti i pazienti devono essere sistematicamente inseriti nella base di dati di SIRIS e di Swissnoso anche se solo l'1 % circa sviluppa una SSI. Il tempo necessario al personale sanitario per questa operazione è stato stimato in circa 160 ore/100 pazienti, ossia in circa il 5 % ETP. Molte ore di lavoro dedicate alla registrazione dei dati potrebbero essere risparmiate e investite nella prevenzione delle infezioni. Il presente progetto è riuscito a fornire una base sufficiente per impostare un progetto di questo tipo, ossia per evitare la doppia registrazione e in ultima analisi affidarsi ai dati SIRIS per la sorveglianza delle SSI ortopediche.

## Conclusioni

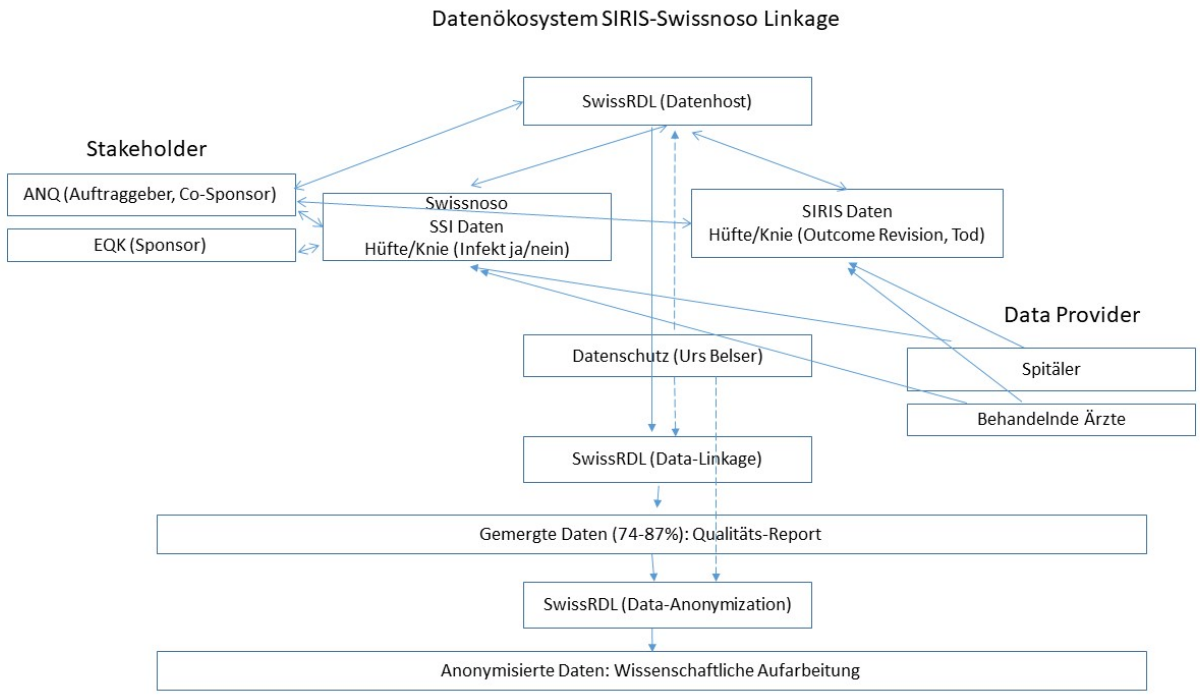
1. Questa integrazione dimostra che tali operazioni sono fattibili e contribuiscono a migliorare la qualità nell'intento di prevenire le SSI nella chirurgia ortopedica. Il presente concetto può essere utilizzato come modello per ulteriori abbinamenti tra basi di dati.
2. Il vantaggio di ospitare entrambe le basi di dati nella stessa sede è risultato cruciale ai fini del successo del progetto.
3. La forte associazione tra SSI di organo/spazio (secondo Swissnoso) e un aumentato rischio di mortalità a 10 anni è stata una sorpresa. Ciò evidenzia che la prevenzione delle SSI non solo riduce significativamente la morbilità, ma anche la mortalità, anche ad anni di distanza dall'intervento. Incoraggia dunque a nuove azioni volte a implementare l'attuale attività di riduzione delle SSI dopo la chirurgia protesica, concentrandosi su parametri di processo – per esempio la decolonizzazione preoperatoria dello *Staphylococcus aureus*, la tempistica della profilassi antimicrobica e il controllo perioperatorio del glucosio.

# 1 Introduction

In Switzerland, the National Association for Quality Development in Hospitals and Clinics (ANQ) currently manages two cohorts/registers that partially overlap: The Swissnoso Wound Infection Surveillance for prosthetic hip and knee surgery and the SIRIS Implant Registry for hip and knee. Therefore, certain basic data are collected and processed twice. Linkage of these two data sets could lead to an enormous gain in quality and possibly also to relevant scientific findings due to the different focus on the Swissnoso side the outcome infection; on the SIRIS side the outcomes revision surgery/implant failure and death). Even if this seems simple at first glance, a closer look reveals that this data ecosystem (depicted in figure 1) consists of different players, some of whom have complex relationships with each other. The primary stakeholders are the ANQ (client for both data collections) and the Swiss Federal Quality Commission (FQC), which is the sponsor that makes the consolidation of the data possible in the first place. Shown on the right are the primary data providers, the hospitals and treating physicians, who enter the data in the respective databases (Swissnoso, SIRIS; shown in the center). The primary outcome is a quality report that describes the work and the result in connection with the linkage. Swiss-RDL is involved here, an institute of the University of Bern, which hosts both databases. A possible secondary endpoint is a scientific report, once the data has been anonymized. Due to the complex data ecosystem, a data protection officer was involved to describe the legal framework regarding data protection in connection with this work.

# 2 Merging SIRIS - Swissnoso databases

Figure 1: Data ecosystem of the SIRIS-Swissnoso Linkage project



# 3 Probabilistic record linkage

Record linkage is method to combine two data sets, where some records in both sets belong to the same person. In a simple world, each data set has the same unique identifier, for example the social security number. In such a situation, the process of linkage the data sets is a simple step of joining or merging data.

The project of linking data from the Swissnoso to the SIRIS registry does not contain a unique identifier. Therefore, probabilistic record linkage (PRL) methods are applied to match records from one data set with high probability to a record of the second data set. PRL has the advantage of performing an error tolerant linkage. E.g. probabilities can be calculated to match the date of operation with a) full match, b) match on year and month, but a difference of +-3 days, or c) match on month and day, but +-1 year (typo). For this linkage study, we applied the basic PRL methods (ref. Fellegi P, I., & Sunter B, A. (1969). A theory of record linkage. Journal of the American Statistical Association, 64(328), 1183–1210.) using the software package G-Link, developed by Statistics Canada.

The linkage of data sets using PRL is based on the likelihood of two records from different sources belong to the same person, based on non-unique variables, which are available in both data sets.

## 3.1 Preliminary steps – data preparation

The clinics entering data into the Swissnoso surgical site infection registry can define and change the type of operation they want to include into surveillance out of a set of predefined operations. Therefore, primary hip total prothesis and primary partial or total knee prothesis are not necessary recorded for every year in all the clinics.

On the other hand, SIRIS collects all primary hip and knee prothesis since 2012 in all clinics where these operations are done. The registration is mandatory and based on the quality contract with ANQ. Additionally, revisions and reoperations must be collected as well.

## 3.2 Harmonization of clinics

First, the clinics in both registries were harmonized. As there was no unique business ID available, the matching of clinics had to be done with open text matching. Over time, clinics change their name, merge with other clinics, or become part of a hospital group or close down. All these changes had to be handled and harmonized in SIRIS and Swissnoso to generate a match table with a unique ID for the service unit.

Furthermore, to create a harmonize hospital list another challenge had to be considered. As the Swissnoso registration year starts in October and ends in September, changes of hospital names and units were adapted for the start of the registration year in October. The SIRIS registry year on the other hand, starts like the calendar year in January. This discrepancy was resolved by merging several clinics into an aggregated group.

## 3.3 Variables used for the probabilistic record linkage

Only variables available in both data sets can be used for the record linkage phase. We included the following variables for the linkage:

| Characteristic |
|---|
| Intervention type (hip or knee) |
| Date of Intervention |
| Harmonized clinic ID |
| Flag for aggregated clinic IDs |
| Code for clinics with different locations, as surgeons often operated in several locations |
| Gender |
| Date of birth (primary operation) |
| Date of birth (revision) |
| Height |
| Weight |
| Flag if case was expected to be matched to other registry (e.g. SIRIS cases are expected to be found in Swissnoso only if the respective clinic was registering this operation in the respective year |

## 3.4 Standardisation of variables

The variables used for the linkage process underwent a thorough data management process. The aim of this step is to make sure the variables used for the linkage had the same structure and format. For example, the date of operation or the date of birth need to be formatted in the same way (DDMMYY), or the codes for gender must be identical in both data sets.

## 3.5 Description of data sets used for linkage

### 3.5.1 SIRIS dataset

We exported all cases from the SIRIS registry with intervention date between 01.01.2012 and 30.09.2022. Each record represents a primary hip or knee operation. The SIRIS dataset consisted of 390’907 records, with 215’678 hip and 175’229 knee operations.

Inclusion criteria were primary hip or primary knee arthroplasty.

Exclusion criteria: SIRIS cases, where the respective Swissnoso clinic did not report this operation in some years, or non-elective SIRIS operations (fractures), as they were not included in Swissnoso.

| | |
|---|---|
| Total cases recorded in SIRIS in study period | 390'907 |
| Excluded, e.g. as Swissnoso clinics did not report THA for some years | - 130'041 |
| Excluded, as Swissnoso only records elective operations (fractures excluded) | -20'194 |
| *Included SIRIS cases for linkage* | ***240'672*** |

### 3.5.2 Swissnoso dataset

We exported all cases from the Swissnoso registry with an intervention date between 01.01.2012 and 30.09.2022. Each record represents a case. The Swissnoso data set consisted of 207’348 records, with 120’356 hip and 86’992 knee implant operations.

Inclusion criteria were elective primary hip or primary knee arthroplasty.

Exclusion criteria: Swissnoso cases in clinics which did not report in SIRIS in the respective year.

| | |
|---|---|
| Total cases recorded in Swissnoso in study period | *207'348* |
| Excluded, e.g. as clinics did not report in SIRIS for respective year | - 3'244 |
| *Included Swissnoso cases for linkage* | ***204'104*** |

### 3.5.3 Indexing – candidates for linked set

Potentially, each record from the SIRIS data set needs be compared to each record from the Swissnoso data set. This Cartesian product would end up in 240'672 x 204'104 = 4.91 $10^{10}$ pairs to be compared. Indexing methods, for example blocking, are applied to exclude all potential pairs of records, where basically none of the linkage variables match. This blocking resulted in a set of less than a million of potentially matching pairs, which were used in the final record linkage process.

### 3.5.4 Rules and weights

For each pair of the potential matching set, all the variables were compared, and a matching and a non-matching probability was calculated. The probabilities were transformed on the log scale and the weights summed up over all variables. This results in a total linkage weight per compared pair. The higher the linkage weights, the higher the likelihood of a pair of records from Swissnoso and SIRIS belonging to the same person.

For the linkage weight, in a final step, cut-offs for definite links, possible links and non-matches were defined.

### 3.5.5 Manual review

If a total linkage weight was defined as a possible link, the records were manually reviewed. The linkage status of 867 pairs has been manually updated after review. For several records data errors could be confirmed and corrected in the database by the hospitals. For instance, about 400 SIRIS cases with wrong gender (1000 cases in Swissnoso are still under review), 30 Swissnoso cases with wrong type of intervention, 150-200 cases with potentially wrong intervention date were sent back to the hospitals for re-checking.

Two hospitals are in the process of an on-site review that basically confirmed that the discordant pairs resulted from the different surveillance systems, with SIRIS having prolonged follow-up (Swissnoso 1 years and currently 3 months) and the mode of detection.

### 3.5.6 Estimation of the linkage quality

As there was no unique ID in the data sets, the true matches cannot not be checked. One of the quality criteria for PRL are the number of alternative links. Alternative links are linked pairs with same or similar total linkage weight. This means, a record from Swissnoso could be matched to more than one record in SIRIS or vice versa. Only few alternative links were found in this study 98.5% of all pairs had no alternative link. This is a great result showing the high linkage quality.

Also, the number of differences in variables of matched pairs, e.g. a match on all variables, but a small difference in date of operation) are a sign of high linkage quality, table below.

Among the linked pairs, the proportion of full match on the most important linkage variables was around 99%. Only the variables height and weight had a lot of missing values.

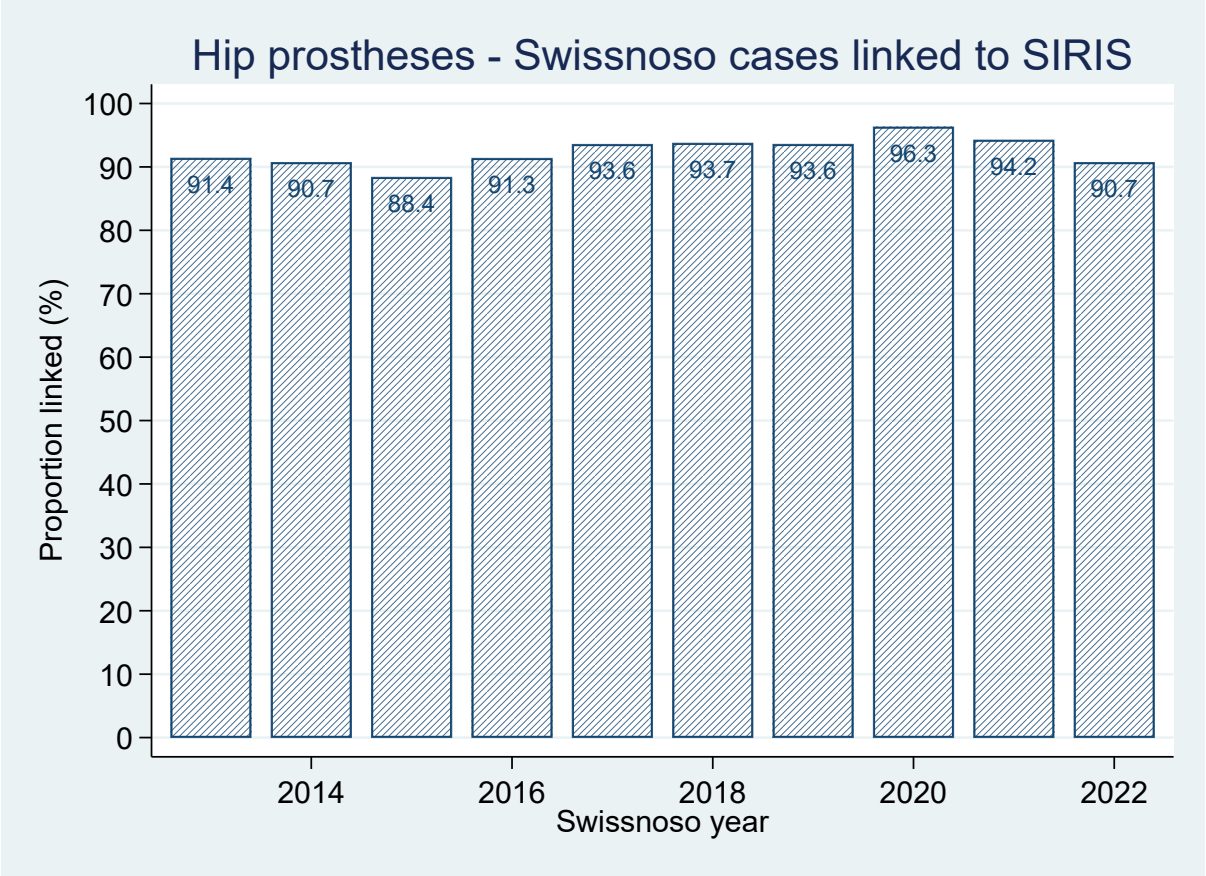
| | Identical | Partial match | Disagree | Missing |
|---|---|---|---|---|
| Clinic | 98.9% | 1.1% 1) | 0.01% | 0.0% |
| Intervention date | 97.9% | 2.1% 2) | 0 | 0 |
| Intervention type (hip/knee) | 99.9% | - | 0.1% | 0 |
| Date of birth | 98.9% | 1.1% 2) | 0 | 0 |
| Gender | 99.3% | | 0.7% | 0 |
| Height | 31.7% | 15.7% 3) | 2.1% | 50.5% |
| Weight | 31.4% | 18.9% 3) | 3.2% | 46.5% |

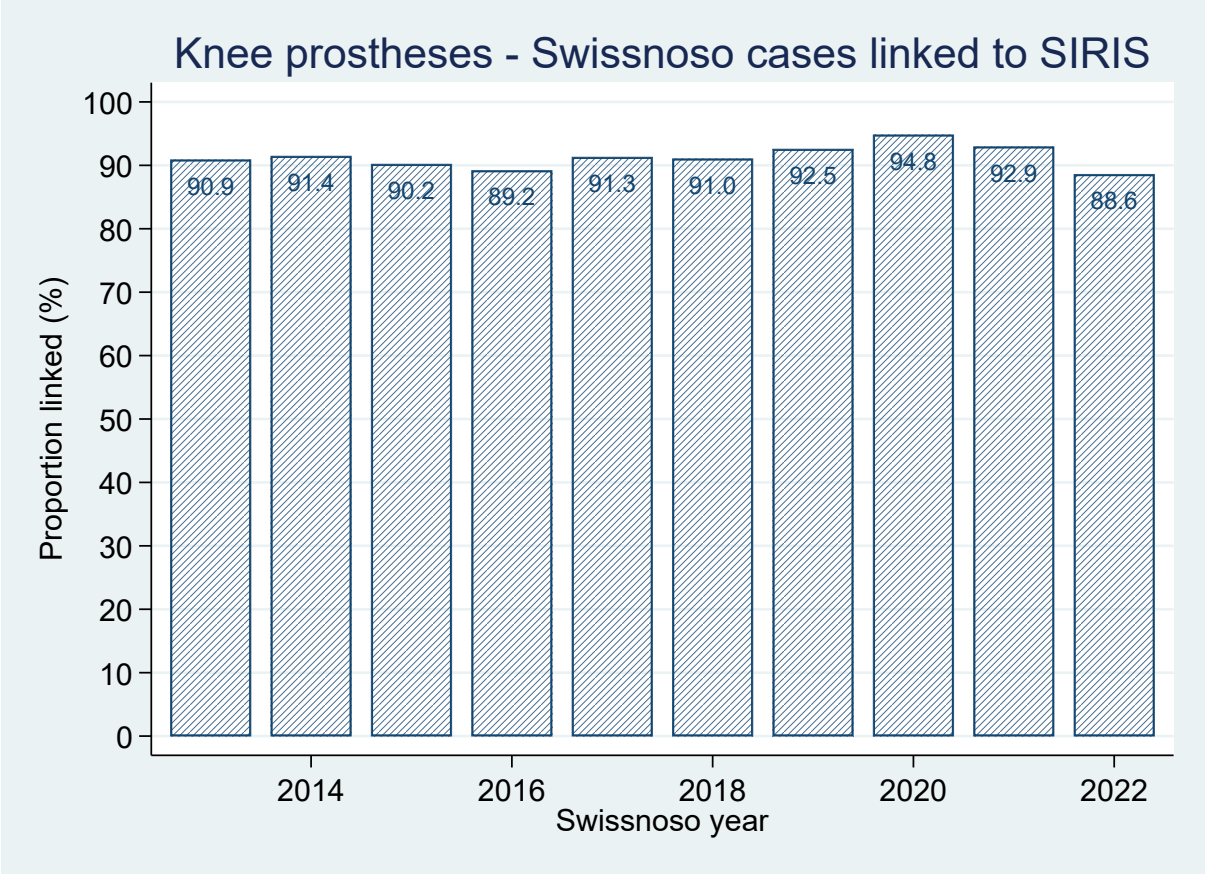
1) hospitals with several locations, affiliated doctors working in different clinics
2) typo error
3) +/- 5 cm, +/- 5 kg

# 4 Results of the probabilistic record linkage Swissnoso - SIRIS

## 4.1 Linking Swissnoso to SIRIS

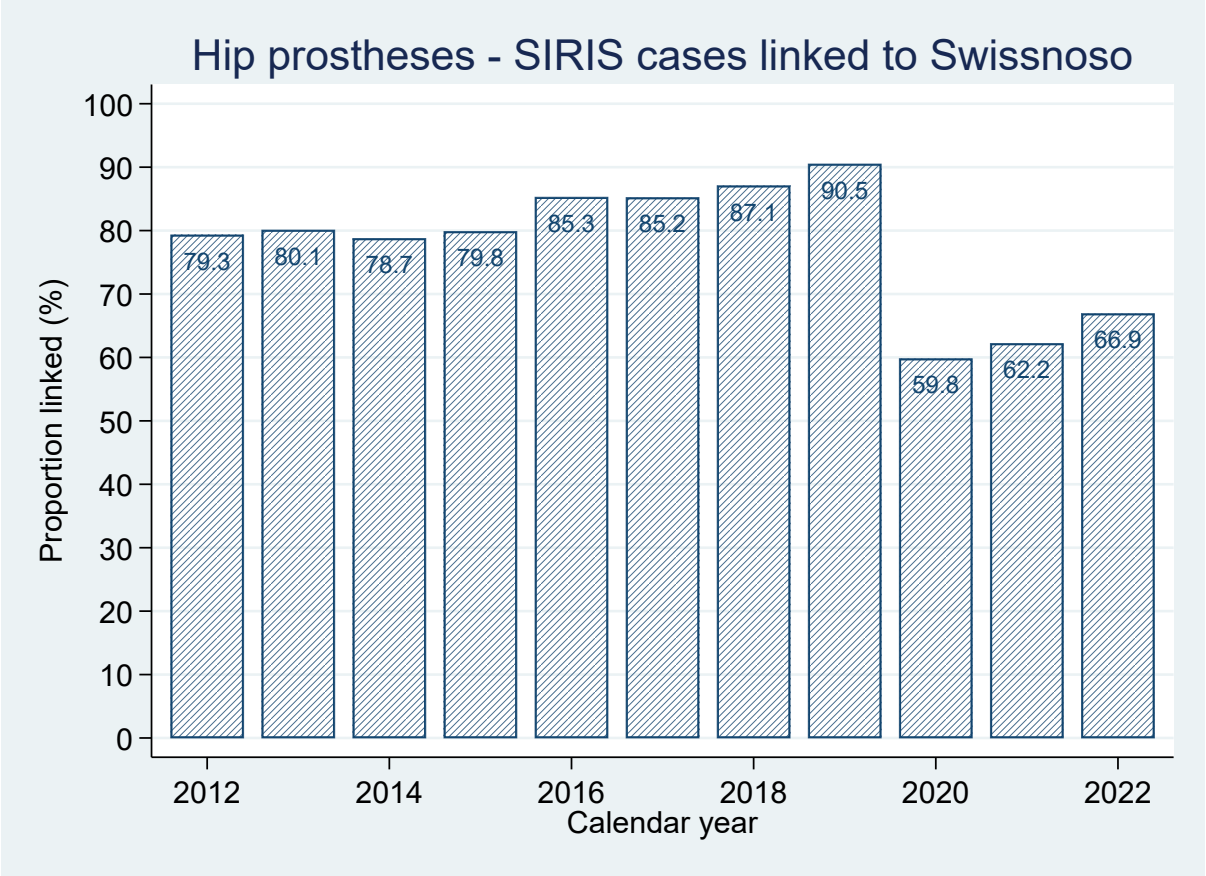
Overall, 178’325 out of 204’104 (87.4%) included Swissnoso cases were linked to a SIRIS case (hip 87.5%, knee 87.2%). As the SIRIS registry started in September 2012 and gradually included clinics in Switzerland, the registration hip and knee surgery in 2012 was incomplete. Therefore, many Swissnoso cases of 2012 could not be linked to SIRIS. The linkage without 2012 data (i.e. only 2013-2022) leads to an overall linkage proportion of 91.9% (hip 92.4%, knee 91.3%). Data for 2012 are not shown in the graphs below.

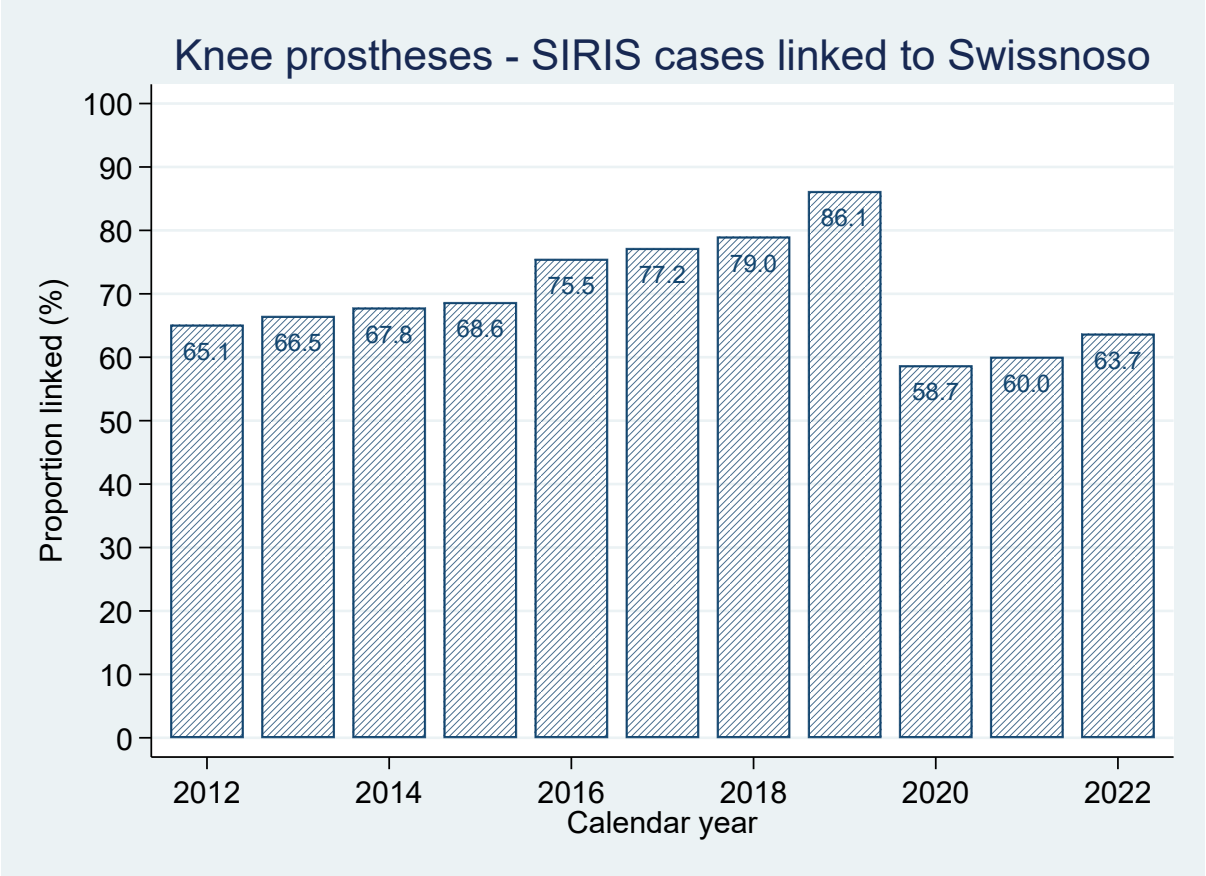

Hip prostheses - Swissnoso cases linked to SIRIS
Proportion linked (%)
0
10
20
30
40
50
60
70
80
90
100
91.4
90.7
88.4
91.3
93.6
93.7
93.6
96.3
94.2
90.7
2014
2016
2018
2020
2022
Swissnoso year


Knee prostheses - Swissnoso cases linked to SIRIS
Proportion linked (%)
0
10
20
30
40
50
60
70
80
90
100
90.9
91.4
90.2
89.2
91.3
91.0
92.5
94.8
92.9
88.6
2014
2016
2018
2020
2022
Swissnoso year

### 4.2 Linking SIRIS to Swissnoso

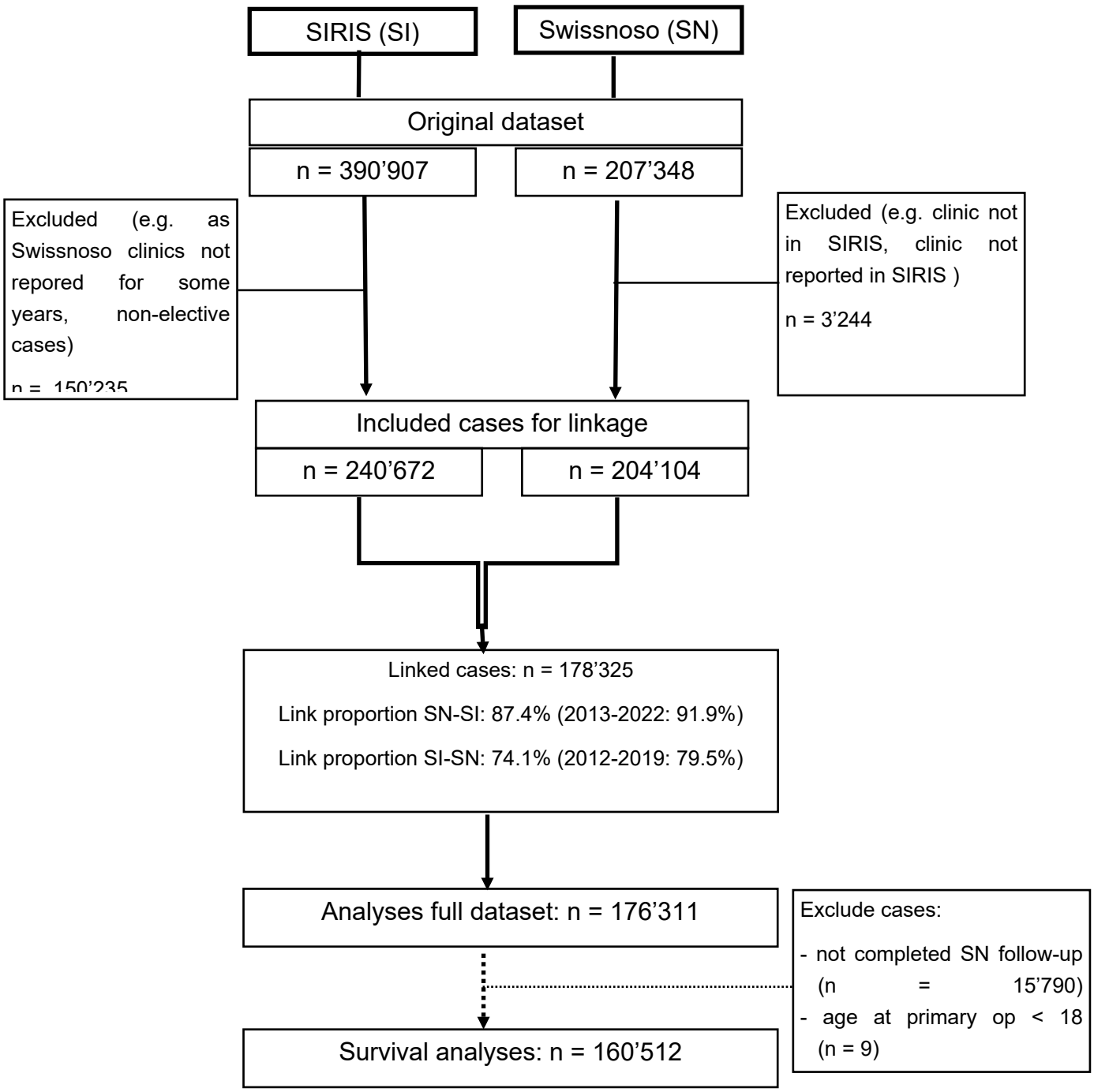
Overall, 178’325 out of 240’672 (74.1%) included SIRIS cases could be linked to a Swissnoso case (hip 77.4%, knee 70.0%). In the years 2020-2022, due to the COVID pandemic, registering cases for Swissnoso were suspended for some months, thus linkage proportions for SIRIS cases to Swissnoso were substantially lower for those years. Looking only at the years 2012 up to 2019, the linkage proportion increases to 79.5% (hip 83.8%, knee 74.1%).



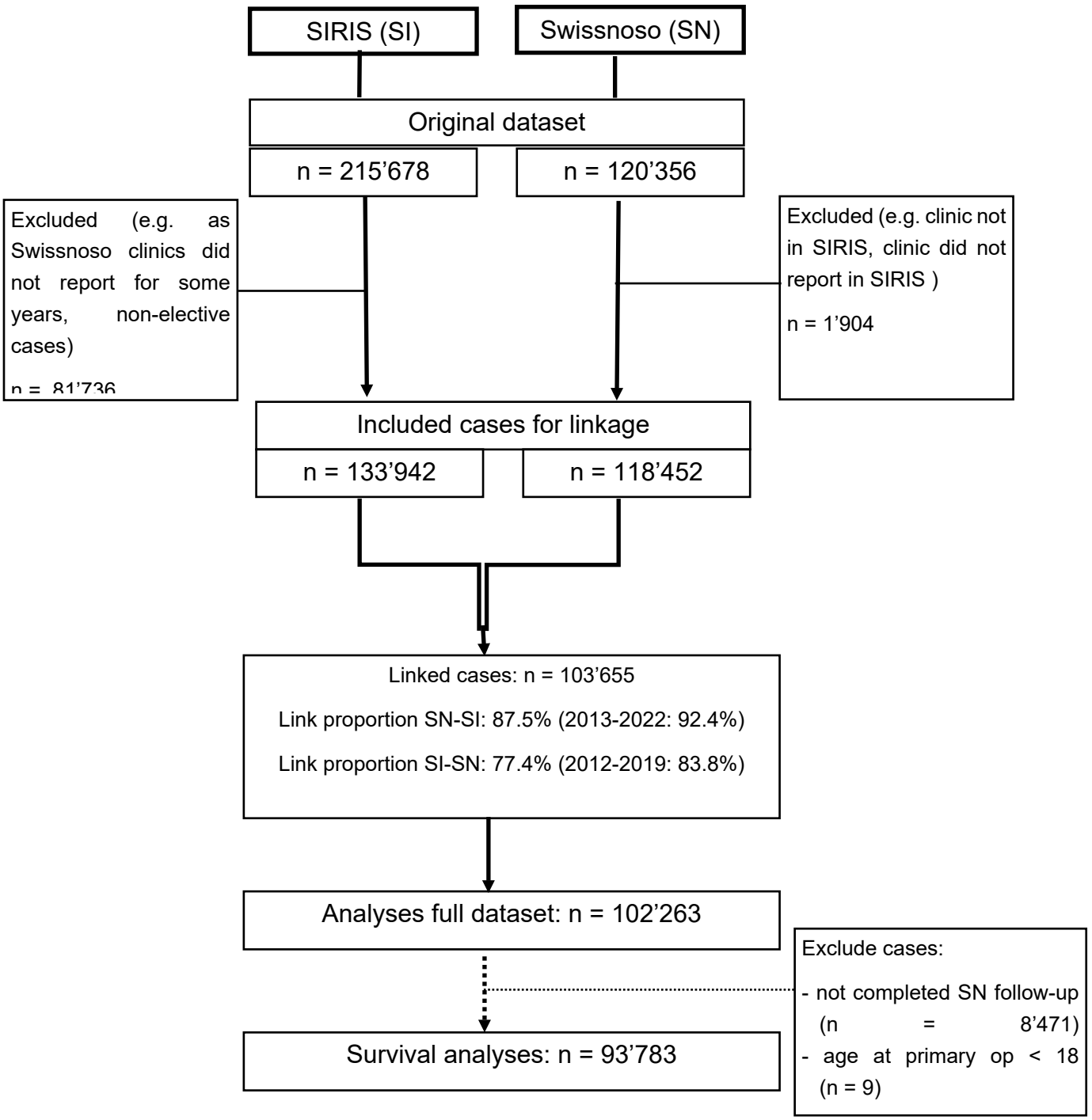

Knee prostheses - SIRIS cases linked to Swissnoso
Proportion linked (%)
100
90
80
70
60
50
40
30
20
10
0
65.1
66.5
67.8
68.6
75.5
77.2
79.0
86.1
58.7
60.0
63.7
2012
2014
2016
2018
2020
2022
Calendar year

## FLOWCHART WITH INCLUSIONS, EXCLUSIONS AND NUMBER OF CASES

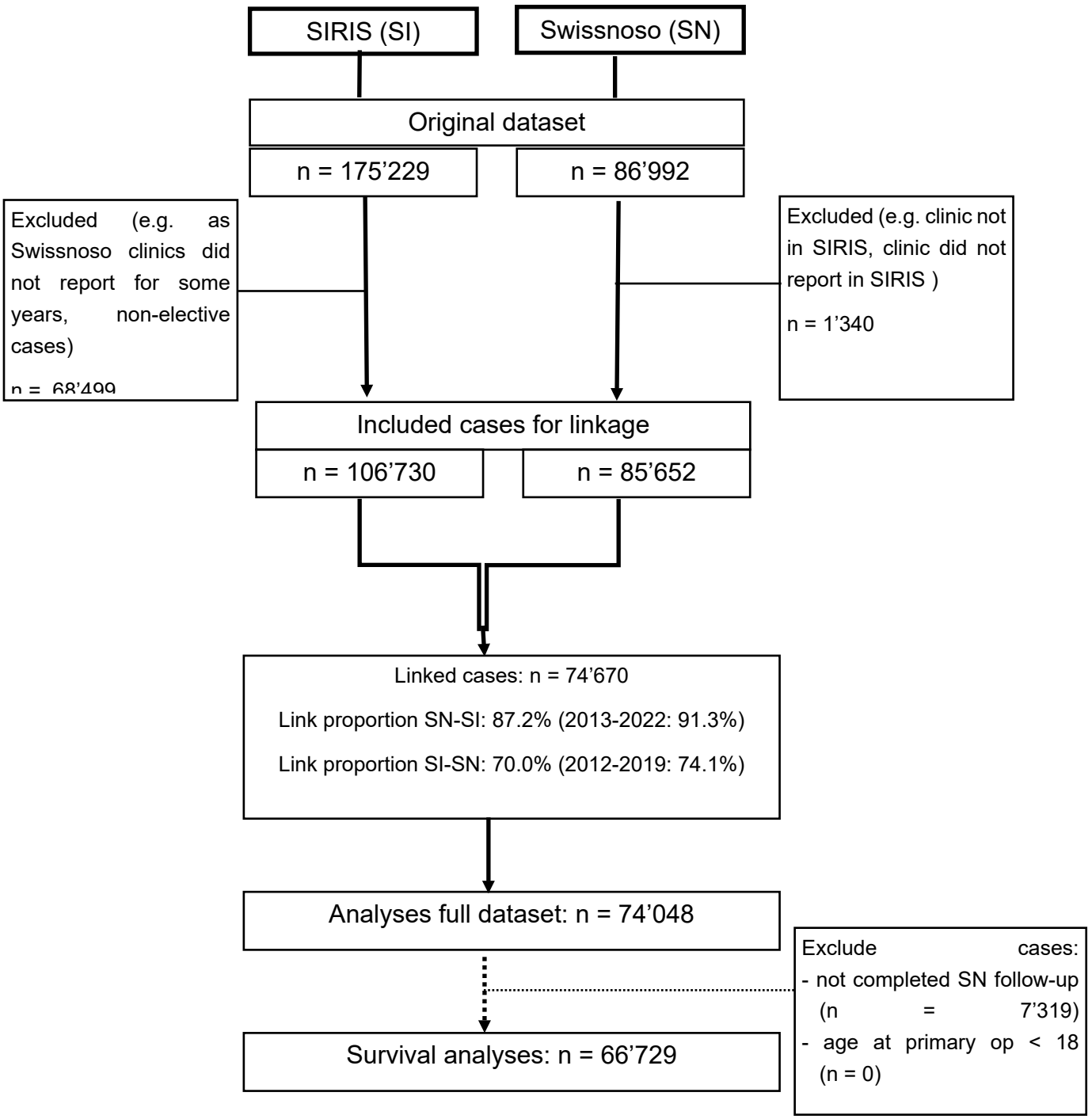
### Hip and knee prostheses



## Hip prostheses



## Knee prostheses



## PATIENT CHARACTERISTICS OF STUDY POPULATION BY INFECTION STATUS

| | HIP | | KNEE | |
|---|---|---|---|---|
| | **Swissnoso organ/space infection** | | **Swissnoso organ/space infection** | |
| | **no** | **yes** | **no** | **yes** |
| TOTAL N (%) | 101'485 (100.0%) | 778 (100.0%) | 73'677 (100.0%) | 371 (100.0%) |
| Gender N (%) | | *p= <0.001+* | | *p= <0.001+* |
| Male | 49'336 (48.6%) | 454 (58.4%) | 30'036 (40.8%) | 219 (59.0%) |
| Female | 52'149 (51.4%) | 324 (41.6%) | 43'641 (59.2%) | 152 (41.0%) |
| Age at primary intervention | | *p= 0.098++* | | *p= 0.933++* |
| Mean (IQR) | 68.2 (60.8-76.4) | 68.9 (61.7-77.7) | 69.0 (62.2-76.0) | 68.9 (61.6-76.2) |
| Age-group at intervention N (%) | | *p= 0.227+* | | *p= 0.444+* |
| <40 | 1'299 (1.3%) | 9 (1.2%) | 110 (0.2%) | 1 (0.3%) |
| 40-59 | 22'075 (21.8%) | 168 (21.6%) | 13'485 (18.3%) | 75 (20.2%) |
| 60-69 | 29'558 (29.1%) | 221 (28.4%) | 24'472 (33.2%) | 124 (33.4%) |
| 70-79 | 33'743 (33.2%) | 243 (31.2%) | 26'351 (35.8%) | 119 (32.1%) |
| 80-89 | 13'986 (13.8%) | 127 (16.3%) | 9'002 (12.2%) | 52 (14.0%) |
| ≥90 | 824 (0.8%) | 10 (1.3%) | 257 (0.3%) | 0 (0.0%) |
| Body mass index (BMI) | | *p= <0.001++* | | *p= <0.001++* |
| Mean (IQR) | 27.3 (23.9-30.1) | 31.1 (26.2-35.0) | 29.3 (25.4-32.4) | 31.6 (26.9-36.0) |
| BMI group N (%) | | *p = <0.001+* | | *p= <0.001+* |
| <18.5 underweight | 981 (1.0%) | 3 (0.4%) | 211 (0.3%) | 1 (0.3%) |
| 18.5-<25 healthy weight | 23'338 (23.0%) | 107 (13.8%) | 10'802 (14.6%) | 37 (10.0%) |
| 25-<30 overweight | 27'417 (27.0%) | 163 (20.9%) | 19'425 (26.4%) | 68 (18.3%) |
| 30-<40 obesity | 16'654 (16.4%) | 246 (31.6%) | 17'922 (24.3%) | 106 (28.6%) |
| ≥40 extreme obesity | 1'195 (1.2%) | 59 (7.6%) | 2'050 (2.8%) | 30 (8.1%) |
| unknown | 31'900 (31.4%) | 200 (25.7%) | 23'267 (31.6%) | 129 (34.7%) |

| | HIP | | KNEE | |
|---|---|---|---|---|
| ASA Score N (%) | | *p= <0.001+* | | *p= <0.001+* |
| 1 normal healthy patient | 12'802 (12.6%) | 39 (5.0%) | 6'403 (8.7%) | 18 (4.8%) |
| 2 mild systemic disease | 61'022 (60.1%) | 371 (47.7%) | 44'665 (60.6%) | 185 (49.9%) |
| 3 severe systemic disease | 26'527 (26.1%) | 354 (45.5%) | 21'952 (29.8%) | 162 (43.7%) |
| 4 severe syst. dis. (threat to life) | 626 (0.6%) | 12 (1.6%) | 286 (0.4%) | 5 (1.4%) |
| 5 moribund patient | 23 (0.02%) | 1 (0.1%) | 13 (0.02%) | 0 (0.0%) |
| unknown | 485 (0.5%) | 1 (0.1%) | 358 (0.5%) | 1 (0.3%) |

Test for heterogeneity between groups

\+ CHI squared test

++ Wilcoxon rank sum test

## 4.3 INFECTION STATUS IN SIRIS AND IN SWISSNOSO

Infections will be registered in Swissnoso only during the follow-up period, which was 1 year after the hip or knee primary intervention. All hip and knee operations after September 30, 2021 only have 90 days follow-up. Infections after that period will not be detected by Swissnoso. In the SIRIS program, the registration of revisions (and infections) has theoretically no end date. Thus, to compare infection status between Swissnoso and SIRIS, we should focus on infections that occur within the Swissnoso follow-up period, and on cases with completed Swissnoso follow-up.

### 4.3.1 Infections within Swissnoso follow-up period and only cases with completed Swissnoso Follow-up

***All infections (superficial, deep wound and organ/space infections)***

Overall infections (Hip + Knee)

| | SIRIS pos. | SIRIS neg. | |
|---|---|---|---|
| Swissnoso pos. | 696 | 992 | 1’688 |
| Swissnoso neg. | 185 | 158’648 | 158’833 |
| | 881 | 159’640 | 160’521 |

McNemar p-value: <0.001, Pearson chi-squared p-value: <0.001

Hip infections

| | SIRIS pos. | SIRIS neg. | |
|---|---|---|---|
| Swissnoso pos. | 469 | 634 | 1’103 |
| Swissnoso neg. | 106 | 92’583 | 92’689 |
| | 575 | 93’217 | 93’792 |

McNemar p-value: <0.001, Pearson chi-squared p-value: <0.001

The study group decided to use only data on organ/space infection for the analyses.

Knee infections

| | SIRIS pos. | SIRIS neg. | |
|---|---|---|---|
| Swissnoso pos. | 227 | 358 | 585 |
| Swissnoso neg. | 79 | 66’065 | 66’144 |
| | 306 | 66’423 | 66’729 |

McNemar p-value: <0.001, Pearson chi-squared p-value: <0.001

The above tables show all infection depths. However, in SIRIS, infections are actually only registered if a revision or at least a re-operation has taken place, and the implant is affected. Thus, infections like superficial infections without revision of the implant are not necessarily registered by SIRIS.

***Swissnoso organ/space infection: how many detected in SIRIS?***

A complete 2 by 2 table for organ/space infections is not possible because SIRIS does not include superficial infections and does not distinguish between deep wound and organ/space infections

Overall organ/space infections (Hip + Knee)

| | SIRIS pos. | SIRIS neg. | |
|---|---|---|---|
| Swissnoso pos. | 683 (59.4%) | 466 (40.6%) | 1’149 |
| Swissnoso neg. | - | - | - |
| | | | |

Hip organ/space infections

| | SIRIS pos. | SIRIS neg. | |
|---|---|---|---|
| Swissnoso pos. | 452 (58.1%) | 326 (41.9%) | 778 |
| Swissnoso neg. | - | - | - |
| | | | |

Knee organ/space infections

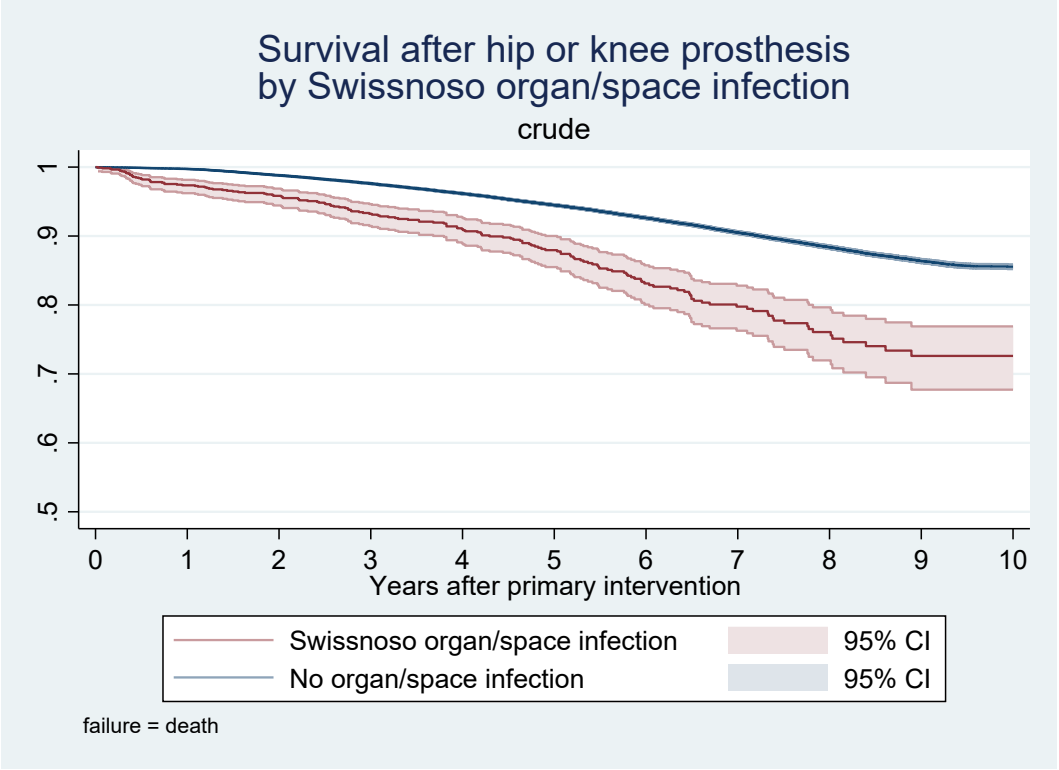
| | SIRIS pos. | SIRIS neg. | |
|---|---|---|---|
| Swissnoso pos. | 231 (62.3%) | 140 (37.7%) | 371 |
| Swissnoso neg. | - | - | - |
| | | | |

### 4.3.2 SURVIVAL BY SWISSNOSO ORGAN/SPACE INFECTION STATUS - FIRST RESULTS

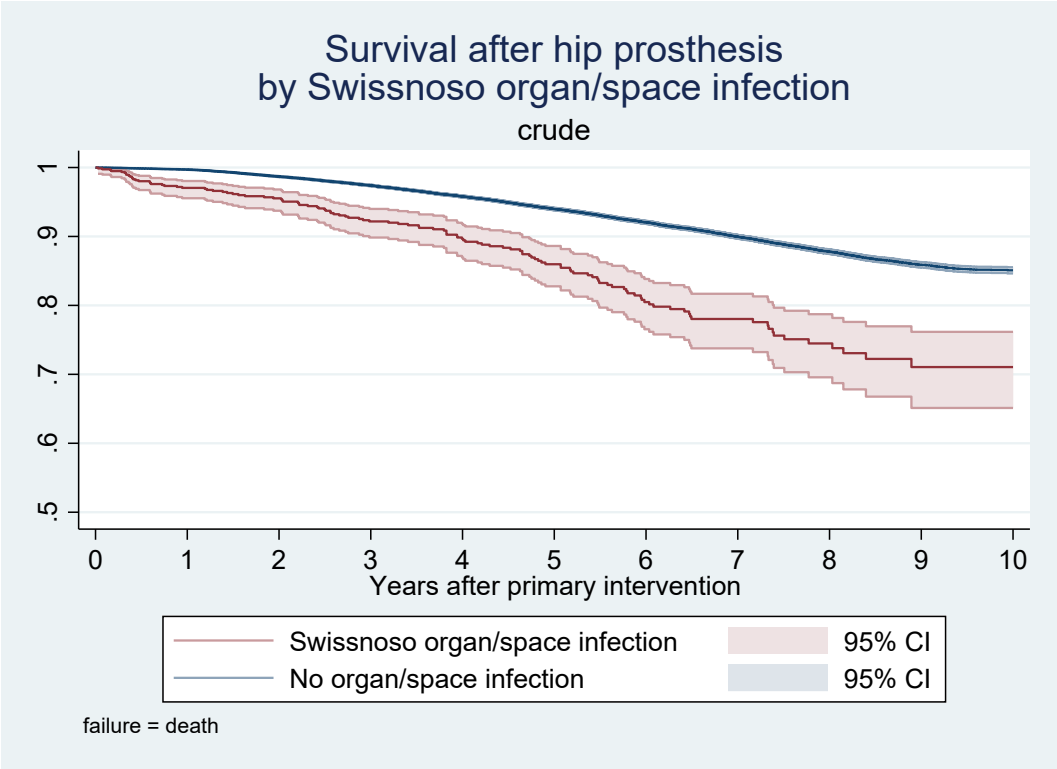
KAPLAN-MEIER-GRAPHS – ORIGIN = DATE OF PRIMARY INTERVENTION

***Overall***

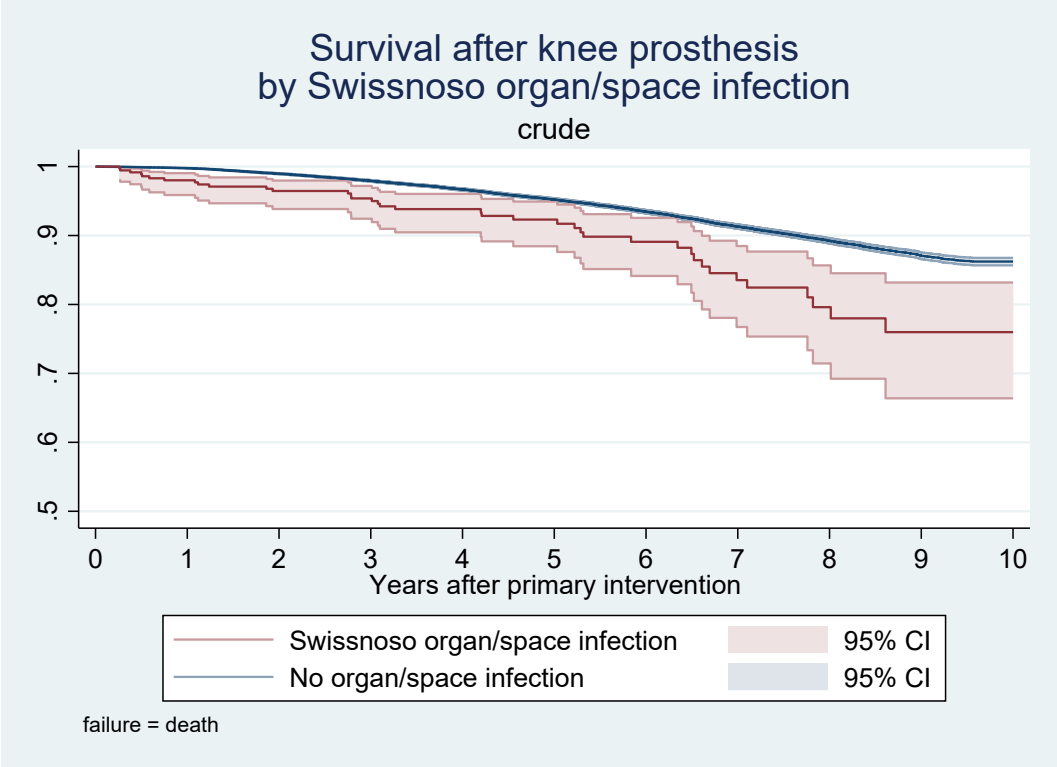
Hip and knee



Hip


Survival after hip prosthesis
by Swissnoso organ/space infection
crude
1
.9
.8
.7
.6
.5
0
1
2
3
4
5
6
7
8
9
10
Years after primary intervention
Swissnoso organ/space infection
No organ/space infection
95% CI
95% CI
failure = death

Knee


Survival after knee prosthesis
by Swissnoso organ/space infection
crude
1
.9
.8
.7
.6
.5
0
1
2
3
4
5
6
7
8
9
10
Years after primary intervention
Swissnoso organ/space infection
No organ/space infection
95% CI
95% CI
failure = death

WEIBULL PARAMETRIC REGRESSION MODELS FOR SURVIVAL DATA

| HIP | Univariable | | Multivariable | |
|---|---|---|---|---|
| | Hazard ratio * | | Hazard ratio * | |
| | HR (95% CI) | p-value | HR (95% CI) | p-value |
| Swissnoso organ/space infection | | *<0.001* | | *<0.001* |
| No | 1 (Ref.) | | 1 (Ref.) | |
| Yes | **2.47 (2.06-2.96)** | **<0.001** | **2.11 (1.76-2.54)** | **<0.001** |
| Gender | | *<0.001* | | *<0.001* |
| Male | 1 (Ref.) | | 1 (Ref.) | |
| Female | 0.85 (0.81-0.89) | < 0.001 | 0.65 (0.62-0.68) | < 0.001 |
| Age at primary intervention | | *<0.001* | | *<0.001* |
| <50 | 0.46 (0.31-0.68) | <0.001 | 0.54 (0.36-0.81) | 0.003 |
| 50-54 | 0.67 (0.49-0.91) | 0.01 | 0.74 (0.54-1.02) | 0.06 |
| 55-59 | 0.89 (0.70-1.13) | 0.33 | 0.94 (0.74-1.19) | 0.58 |
| 60-64 | 1 (Ref.) | | 1 (Ref.) | |
| 65-69 | 1.48 (1.23-1.77) | <0.001 | 1.41 (1.18-1.69) | <0.001 |
| 70-74 | 2.45 (2.08-2.88) | <0.001 | 2.23 (1.89-2.62) | <0.001 |
| 75-79 | 3.38 (2.88-3.96) | <0.001 | 2.90 (2.47-3.41) | <0.001 |
| 80-84 | 6.20 (5.31-7.24) | <0.001 | 5.01 (4.28-5.86) | <0.001 |
| 85-89 | 11.45 (9.80-13.4) | <0.001 | 8.73 (7.45-10.2) | <0.001 |
| ≥90 | 22.32 (19.0-26.2) | <0.001 | 15.97 (13.6-18.8) | <0.001 |
| Body mass index (BMI) | | *0.004* | | *<0.001* |
| <18.5 underweight | 1.55 (1.21-1.98) | <0.001 | 1.92 (1.51-2.46) | <0.001 |
| 18.5-<25 healthy weight | 1.08 (1.00-1.17) | 0.04 | 1.13 (1.05-1.23) | 0.001 |
| 25-<30 overweight | 1 (Ref.) | | 1 (Ref.) | |
| 30-<40 obesity | 0.99 (0.75-1.24) | 0.77 | 1.03 (0.94-1-12) | 0.52 |
| ≥40 extreme obesity | 0.96 (0.75-1.24) | 0.78 | 1.17 (0.91-1.51) | 0.22 |

| HIP | Univariable | | Multivariable | |
|---|---|---|---|---|
| ASA Score | | *<0.001* | | *<0.001* |
| 1 | 1 (Ref.) | | 1 (Ref.) | |
| 2 | 3.31 (2.85-3.86) | <0.001 | 2.00 (1.71-2.34) | <0.001 |
| 3 | 10.55 (9.06-12.3) | <0.001 | 4.09 (3.50-4.79) | <0.001 |
| ≥4 | 26.04 (21.1-32.2) | <0.001 | 8.37 (6.74-10.4) | <0.001 |

* Hazard ratio (HR) from Weibull parametric regression model for survival data

| KNEE | Univariable | | Multivariable | |
|---|---|---|---|---|
| | Hazard ratio * | | Hazard ratio * | |
| | HR (95% CI) | p-value | HR (95% CI) | p-value |
| Swissnoso organ/space infection | | *<0.001* | | *0.002* |
| No | 1 (Ref.) | | 1 (Ref.) | |
| Yes | **1.97 (1.43-2.71)** | **<0.001** | **1.64 (1.19-2.26)** | **0.002** |
| Gender | | *<0.001* | | *<0.001* |
| Male | 1 (Ref.) | | 1 (Ref.) | |
| Female | 0.76 (0.71-0.81) | <0.001 | 0.63 (0.59-0.67) | <0.001 |
| Age at primary intervention | | *<0.001* | | *<0.001* |
| <50 | 0.40 (0.15-1.10) | 0.07 | 0.46 (0.17-1.24) | 0.12 |
| 50-54 | 0.97 (0.64-1.48) | 0.89 | 1.06 (0.69-1.61) | 0.79 |
| 55-59 | 0.70 (0.50-1.00) | 0.05 | 0.74 (0.52-1.04) | 0.08 |
| 60-64 | 1 (Ref.) | | 1 (Ref.) | |
| 65-69 | 1.45 (1.15-1.82) | 0.001 | 1.39 (1.11-1.75) | 0.004 |
| 70-74 | 2.17 (1.76-2.67) | <0.001 | 2.04 (1.65-2.52) | <0.001 |
| 75-79 | 3.47 (2.84-4.24) | <0.001 | 3.15 (2.58-3.86) | <0.001 |
| 80-84 | 6.00 (4.92-7.31) | <0.001 | 5.24 (4.29-6.40) | <0.001 |
| 85-89 | 11.62 (9.53-14.2) | <0.001 | 9.91 (8-10-12.1) | <0.001 |
| ≥90 | 20.30 (16.5-25.0) | <0.001 | 16.88 (13.6-20.9) | <0.001 |
| Body mass index (BMI) | | *0.005* | | *0.08* |
| <18.5 underweight | 1.51 (0.83-2.74) | 0.17 | 1.14 (0.63-2.06) | 0.68 |
| 18.5-<25 healthy weight | 1.19 (1.06-1.34) | 0.004 | 1.17 (1.04-1.32) | 0.01 |
| 25-<30 overweight | 1 (Ref.) | | 1 (Ref.) | |
| 30-<40 obesity | 0.96 (0.86-1.07) | 0.44 | 1.12 (1.01-1.25) | 0.03 |
| ≥40 extreme obesity | 0.89 (0.70-1.14) | 0.36 | 1.25 (0.98-1.60) | 0.07 |

| KNEE | Univariable | | Multivariable | |
|---|---|---|---|---|
| ASA Score | | *<0.001* | | *<0.001* |
| 1 | 1 (Ref.) | | 1 (Ref.) | |
| 2 | 2.42 (1.96-2.99) | <0.001 | 1.64 (1.33-2.03) | <0.001 |
| 3 | 6.34 (5.14-7.81) | <0.001 | 3.06 (2.47-3.79) | <0.001 |
| ≥4 | 14.70 (10.4-20.8) | <0.001 | 7.01 (4.94-9.95) | <0.001 |

* Hazard ratio (HR) from Weibull parametric regression model for survival data

# 5 Budget

The budget was tight, but covered the planned activities as submitted to FQC. However, additional cost for legal issues concerning data protection, on-site validation, and higher administration cost for the reporting exceed the budget.

| | Budget | Cost | Balance | Subsidies |
|---|---|---|---|---|
| Preparation of project | 5'000 | 5'000 | | EQK |
| Merging databases | 25'000 | 25'000 | 0 | EQK |
| | | | 0 | |
| Analyses of the content of the merged databases | 25'000 | 25'000 | 0 | ANQ, SwissRDL, Swissnoso |
| Reporting | 5'000 | 5'000 | 0 | ANQ, SwissRDL, Swissnoso |
| Data Protection work-load | 0 | 7'000 | -7'000 | |
| Validation, meetings, progress reports, final report, administration | 0 | 8'000 | -8'000 | |
| Total | 60'000 | 75'000 | -15'000 | |

The framework that EQK only covers 50% of the total cost is a large hurdle to continue such projects. We negotiate with our partners ANQ, SIRIS and SwissRDL to cover the other 50% as outlined in the proposal. However, the framework of EQK subsidies should be considered given the large impact such merger could achieve. The non-budgeted cost requires further negotiations.

The success of the project was hampered by the fact, that data protection issues, the unplanned, but important on-site chart-review validation process, and the pioneer level of the project increase the cost and exceeded the budget. Similar projects must require a more reasonable budget to complete it even with some non-foreseen challenges.

# 6 Discussion, Conclusions, and next steps

## 6.1 Technical

The technical challenges were very well managed by SwissRDL: The advantage of hosting both databases was a crucial advantage for the success of the project. The partners did know each other very well, that allowed to come to solutions where the financial consequences were not yet clear. This quality project provides proof-of-concept that such mergers are feasible in Switzerland, a milestone in data management in Switzerland.

## 6.2 Validation

The validation process was completed by SwissRDL, and Swissnoso: The discrepancies were largely explained by the different surveillance approaches, the follow-up, and the definition of the case "infection". However, there remained a considerable number of cases that were not traced down to such reasons. Therefore, we went to two hospitals, to solve the issues of discordant pairs by chart review.

## 6.3 Results

Postoperative surgical site infections after orthopedic implant surgery increased the 10-year hazard ratio for mortality by 1.64 in knee surgery ($p=0.002$) and 2.11 in hip surgery ($p<0.001$), and has not only an association within two years after surgery, but up to 10 years. These results underline the importance of SSI prevention, as the mortality after SSIs increases even over the 10 years after surgery. The validation of the results of the SIRIS and Swissnoso data storage added to the validity check of both databases. To our knowledge, such long-term effects on mortality have not been detected yet, and increase the importance of prevention of SSIs. The long-term effect was observed even independent on underlying disease (ASA-score) and age.

# 7 Proposals for further quality improvement on prevention of SSI in orthopedic surgery, based on our project results

(a) This merger provides proof of concept that such mergers are feasible and add to the quality improvement to prevent SSIs in orthopedic surgery. This concept may be used as template for further databases.

(b) The long-term impact of SSIs on mortality was a surprise: It underlines that prevention of SSIs not only significantly decrease morbidity, but also mortality, even years after surgery, It supports new actions to roll out the current activity to decrease SSIs after implant surgery, with focus on process parameters – *S.aureus* decolonization prior surgery, timing of antimicrobial prophylaxis, and perioperative glucose control.

(c) A major step forward to avoid double-entry of data would be to rely on SIRIS data entry, transfer them quarterly to the Swissnoso data to complement the SIRIS dataset with data of microbiology and infection type by the local hospital.

More than 97% of the patients after implant surgery do not develop SSIs. , all patients must be entered in SIRIS AND Swissnoso databasesWe estimate with this linkage that approximately 12 FTE can be saved and allocated to patient care rather than collecting data. Given the high quality of the SIRIS database, Swissnoso could rely on this dataset, and save thousands of working hours for recording the data. This endeavor would be quite costly, given the approval of by SIRIS, workload for SwissRDL, and Swissnoso, but the return of investment would be very quick for the hospitals. However, the burden of the work would rely on Swissnoso, SIRIS and SwissRDL, but the savings at the hospital level