

## Proposal of a Quality Assessment Tool for the Evaluation of the Methodological Quality of Self-controlled Case Series and Self-controlled Risk Interval Study Designs

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### Abstract

Self-Controlled Case Series (SCCS) and Self-Controlled Risk Interval (SCRI) study designs are types of studies where cases act as their controls. They are commonly used by pharmacovigilance to study rare events. There is no existing tool for the assessment of the methodological quality of such studies. Critical appraisal in primary and secondary studies is crucial as it enables the reader to evaluate how the study was elaborated and take this into consideration while analyzing the evidence presented. This paper presents a proposal of an instrument that has been adapted from an already existing tool used for cohort studies and it combines the elements of this tool and the premises of the SCCS and SCRI study designs. It is expected that the tool will help researchers and readers in critically appraising SCCS and SCRI study designs.

**Keywords:** Self-controlled case series; Self-controlled risk interval; Critical appraisal; Pharmacoepidemiology

### Introduction

A Self-controlled Case Series (SCCS) or case series method is an observational epidemiological study design used to study the temporal association between a time varying exposure and a sudden onset of events. It's a study design where the observed cases act as their own controls [1-5].

It was originally developed in 1995 for the evaluation of vaccine safety in pharmacoepidemiology and nowadays it is used in general epidemiology [1,6,7]. It is derivative of a cohort study design where individuals who have experienced the event of interest are observed over time, within a pre-established observation period, where the exposure history and the occurrence of the event of interest are identified. During the observation period, the risk period and the control period are established, which usually do not have the same length of time. The risk period is defined a priori and is considered as the time during or after exposure where the individuals are at a higher or reduced risk of the events of interest after an exposure. The control period constitutes any time within the observation period (before, after or between) the risk period [1,2,8]. For example, in a study to evaluate the risk of GBS after Human Papilloma Virus (HPV) Vaccination in England, the risk period started with vaccination (day 0) and ended on day 91 and a control period considered any time outside the risk period [9].

Normally, information from past events may help define the risk period [1]. For example, in the case of influenza vaccines and the development of Guillain-Barré syndrome (GBS), the prespecified risk period is 42 days after vaccination. This risk period was stipulated after a cluster of GBS cases occurred in the United States in 1976 after the population was vaccinated with A/New Jersey influenza vaccine [10]. During this risk period, it is presumed that there will be increased risk of the vaccinated individuals to develop the GBS and the time after as the control period [1,11].

A SCCS design is suitable for independent recurrent events as well as rare non-recurrent events. Some of the assumptions that make SCCS applicable include: the observed events are rare; the occurrence of an event must not alter the probability of subsequent exposure that is, if the

events are consecutive, they should be independent; the occurrence of the event of interest must not censor or affect the observation period and that the observation period for each individual is independent of the event times. The latter can be violated in the event of death [1,2,4,5,7].

The SCCS estimates the relative incidence (RI) of events of interest in a defined time period after a transient exposure and the control period. The RI is the ratio of events of exposure in the risk period and the control period [1,6,11].

The main advantage of SCCS is that time invariant confounders that act on the standard rates are rigorously controlled. These factors are like: sex, location, genetics, socio economic factors and underlying health condition [1,5,12]. It is also cheaper and easier to collect data since the design only requires cases with the event of interest. Also, as an advantage is the methodological efficiency compared to the cohort design, for example, in the surveillance of adverse events after vaccination, a traditional cohort study may not be applicable for full coverage of the effects since it would be a challenge to recruit unvaccinated controls as the surveillance systems normally collect data on individuals who reported an adverse event. The SCCS requires a small sample of the population to be studied thus it can produce results that are clinically and statistically valid from just a few cases [1,4]. Some of the limitations of the SCCS design include: it does not produce estimates of absolute incidence but only estimates of relative incidence; as one of its assumptions, it requires that the probability of exposure is not affected by the occurrence of an outcome event, the effect of exposure has to be transient, variations over time are not adjusted for,

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it is prone to selection and information bias (normally uses information from surveillance databases). For non-recurrent events, the SCCS design works only when the event risk is small over the observation period [1,12].

The Self-controlled risk interval (SCRI) is a variant of a SCCS design where cases also act as their own controls. There is a risk period and a control interval. The control period is either before or after the exposure. The SCRI design has a reduced control interval, for example, in the case of vaccines, after the risk period is determined; a selected short period is selected before or after vaccination and close to the risk period. The reduced control interval is chosen to avoid time confounding factors like age and seasonality. The control interval is usually similar to the risk period [13,14]. For example, in a study to evaluate the adverse events following varicella vaccine in Taiwan, the risk interval was day 1 to day 42 after vaccination and the control interval was the period between day 43 to day 84 post vaccination [15].

The striking difference between the two study designs is the observation period. In the SCRI design, the index date is the vaccination date, and it is used to define the risk and control period. On the other hand, the SCCS design chooses an observation period independent of the vaccination date and all cases are identified in the observation period [14].

Just like the SCCS, the SCRI design controls for fixed confounding factors like sex, race, genetic factors, preexisting health conditions and geographical locations. For time varying confounders like seasonality and age, there is a need for explicit adjustments, like in the case of vaccines, the adverse effects vary especially among children and can also vary over the follow up period and be confounded with other factors giving a false positive impression of the vaccine effects [13,14]. Unlike SCCS that includes both the vaccinated and unvaccinated individuals in the case of the analysis of adverse effects after vaccination, the SCRI design only includes vaccinated cases [15]. This is the primary strength of the SCRI design as it reduces bias that can arise among the vaccinated and unvaccinated cases [16].

SCCS and SCRI study designs are crucial in epidemiology where other study designs may not be quite suitable like the case of adverse events after vaccination in pharmacovigilance and thus, they require their quality evaluated and reported considering the basic assumptions of such study designs.

In evidence synthesis, the critical appraisal of the studies included is essential so as to access the credibility of the findings which is a consequence of the methodological rigor applied. It also helps to analyze the transparency and reproducibility of the published evidence. The absence of the critical appraisal is a barrier to the consumers of the evidence generated since there is hinderance in the ability to interpret the research findings which consider the strengths and weaknesses of the study in question [17,18].

To the best of our knowledge and after contacting two renowned researchers in SCCS/SCRI design, it came to our knowledge that no specific methodological assessment tool that has been reported and validated for use in evaluating the methodology of SCCS/SCRI designs. In 2018, Wachira and collaborators adapted the New Castle Ottawa Scale for quality assessment of cohort studies to evaluate SCCS study designs in their systematic review of the etiology of Guillain-Barré [19,20]. The present study aims at proposing a methodological quality assessment tool that can be used in quality assessment of SCCS/SCRI study designs.

## Methodology

The quality assessment tool is an adaptation of the Newcastle Ottawa Scale (19) for the quality assessment of cohort studies as presented by Wachira and colleagues and considers the basic assumptions of SCCS/SCRI [21]. The proposal was adapted by V.W and assessed by H.M and M.R. Two other scholars used the tool in their systematic reviews studies [22,23].

There are two approaches that are widely used in the quality assessment of a primary study: the component approach that evaluates the individual items of each domain of the assessment tool and the composite approach that considers the quality scores of each of the domains and gives an overall score [24].

The proposed quality assessment tool is divided into three sections: Selection, Comparability and Outcomes as shown in Table 1. In the Selection section, the tool evaluates the representativeness of the selected cases in the SCCS/SCRI in relation to the total cases coming from the study population, the definition of the cases, the ascertainment of exposure and the absence of the outcome of interest at the start of the observation period. In the comparability section, confounding factors that vary over time are evaluated such as age and seasonality. The study should report if these factors were considered and if any adjustments were made in the analysis of the results. In the outcome section, there is evaluation of the ascertainment of the outcome of interest, clear indication of the risk and control periods and adequacy of the observation periods.

## Results

For the overall/composite assessment in each section, stars are allocated. For section 1, a maximum of three stars can be awarded to a study if the cases are representatives of the cases in the general population like in the case of vaccine safety studies, if there is a clear ascertainment of the exposure of interest and if there is a demonstration that the outcome of interest occurred in the observation period. In section 2, a maximum of two stars can be awarded to a study if it reports that time varying confounders were accounted for or if the follow up period was short enough to mitigate time confounding factors. In section 3, a study can be awarded a maximum of five stars if there is a clear way of confirming the outcome, if the risk and control periods are well stated, if the time in the risk and control periods was long enough for the outcome of interest to be analyzed and if there was complete follow up of the cases or accountability of the cases lost during follow up. In total, a study can be awarded a maximum of 10 stars.

In this first proposal of the assessment tool, the overall assessment of a study can be considered to be of “poor quality” if the study is awarded 3 stars, “moderate quality”, if the study is awarded up to 6 stars and “high quality” if the study gets 7 to 10 stars. This is just a suggestion of how to grade the overall quality of the study evaluated but the users of the tool are at liberty to decide how this can be applied in the studies analyzed depending on the specificities of the research question tackled in those studies.

There were no weights accorded to the sections in the tool thus giving the user the opportunity to be flexible in determining the overall quality of the study taking into consideration the need of the quality assessment and the nature of the evidence synthesis product in question. Table 1 shows the sections of the quality assessment tool, an explanation of the items considered and how to award stars to these items.

Section Selection	Explanation/Guide	Assessment Three stars maximum
<p>Representativeness of the cases</p> <p>a) Truly representative of the average _____ (describe) in the community .</p> <p>b) Somewhat representative of the average _____ in the community .</p> <p>c) Selected group of users, example, volunteers</p> <p>d) No description of the derivation of the cases in the study</p>	<p>The study should show the representativeness of the cases in terms of all cases from the study population. For example, in vaccine safety studies, were the selected cases (people with the outcome of interest) representative of all cases originating from the study population?</p> <p>a) Were all eligible cases included in the study? In the case of vaccine safety studies, were all cases registered for example in a data base of adverse events, reference institution or hospital or was there a clear method of defining who was to be included in the study?</p> <p>b) In case of random sampling, was there a clear method used to define the cases included in the study? Example, In the case of vaccine safety studies were the adverse effects analyzed reported at a predetermined period of interest?</p> <p>c) Was there a certain group of individuals who qualified to be the cases after an exposure and were there any justifications of why that was done?</p> <p>d) No explanation whatsoever of how the cases were included in the follow up.</p>	<p>One star maximum: A study gets a star if meets the requirements for item a or b</p>
<p>Ascertainment of exposure</p> <p>a) Secure record (Example, data base)'</p> <p>b) Structured interview .</p> <p>c) Written self-report</p> <p>d) No description</p>	<p>The study should report how the exposure was ascertained</p> <p>a) Is there a secure record of that shows that there was an exposure? Example, in the case of vaccines, is there a secure database of the vaccines administered, doses, date, batch number ?</p> <p>b) In the absence of a database or secure registries of the exposure of interest, were the cases interviewed to clarify about the exposure, did they show a vaccination card, were the caregivers contacted to confirm the information?</p> <p>c) Did the cases self-report the exposure with no other physical evidence (like a vaccination card)? Example, a self-report of vaccination</p> <p>d) No documented evidence of exposure or self-report.</p>	<p>One star maximum: A study gets a star if it meets the requirements of item a or b.</p>
<p>Demonstration that outcome of interest was not present at start of study</p> <p>a) Yes'</p> <p>b) No</p>	<p>There should be evidence that the outcome of interest occurred during the observation period</p> <p>1. The study should report that the outcome of interest occurred during the observation period</p>	<p>One star maximum: A study gets a star the response is "yes"</p>
<p><b>Comparability</b></p>	<p>One of the most important pillars of self-controlled studies. The study should at least report which of the confounding factors that vary over time were controlled for.</p>	<p>Two stars maximum</p>
<p>Comparability of cases on the basis of the design or analysis</p>	<p>The comparability is inherent of the study design and should be evaluated in detail</p>	<p>Two stars maximum</p>

<p>a) Study controls for _____ (select the most important factor that varies over time; seasonality or age) or the follow-up period was short enough to mitigate time-confounding issues *</p> <p>b) Study controls for any additional factor or justifies why the time varying factors were controlled (This criterion could be modified to indicate specific control for a second important factor that varies over time)*</p>	<p>a) The study should report if a time varying factor such as seasonality or age were controlled in the study. (Some exposures depending on the age or seasonality may give biased results of the outcomes evaluated)</p>	<p>A study can get a star if it meets the requirements of item a or b, or two stars if it meets the requirements of the two.</p>
<p>Outcome</p>	<p>The study should clearly report the outcome of interest</p>	<p>Five stars maximum</p>
<p>Assessment of outcome</p>	<p>The outcome of interest should be evaluated in a valid manner</p>	<p>One star maximum</p>
<p>a) Independent blind assessment* or outcome was measured in a valid and reliable way</p> <p>b) Record linkage*</p> <p>c) Self-report</p> <p>d) No description</p>	<p>a) Were the outcomes evaluated in an independent way (by specialists who were blinded), was a valid and reliable method of evaluation used like a criterion of confirmation of exposure?</p> <p>b) In the case of the use of a database, were there any data linkage between the exposure database and that of outcomes?</p> <p>c) Did the cases self-report the outcomes?</p> <p>d) No description of how the outcome was assessed.</p>	<p>A study get a star if it meets the requirements of item a or b</p>
<p>Risk period stated</p>	<p>One of the observation periods of the SCCS and SCRI designs</p>	<p>One star maximum</p>
<p>a) Yes*/justify the period</p> <p>b) No</p>	<p>a) Was the risk period clearly stated in reference to when the exposure occurred, or the selection of the period justified?</p> <p>b) No statement of the risk period.</p>	<p>A study get a star if the response is “yes”</p>
<p>Control period stated</p>	<p>One of the observation periods of the SCCS and SCRI designs</p>	<p>Maximum of one star</p>
<p>a) Yes*</p> <p>b) No</p>	<p>a) Was the control period clearly stated in reference to the time of exposure or the risk period.</p> <p>b) No statement of the control period.</p>	<p>A study get a star if the response is “yes”</p>
<p>Risk period and control period long enough for outcomes to occur</p>	<p>The risk and control periods should be long enough to observe the outcomes of interest.</p>	<p>One star maximum</p>
<p>a) Yes (select an adequate follow up period for outcome of interest/)*</p> <p>b) No</p>	<p>Was there an adequate follow up?</p> <p>*An adequate follow up is essential to observe the desired outcomes. Generally, the period of risk is determined by previous studies. The study should at least mention why the lengths of the periods of observation were chosen, this information guides in determining if the follow up was sufficient enough for the outcomes to occur.</p>	<p>A study get a star if the response is “yes”</p>
<p>Adequacy of follow up of cases</p>	<p>Significant loss to follow up may be detrimental to the results obtained. A SCCS or SCRI should account for the cases studied.</p>	<p>One star maximum</p>

<p>a) Complete follow up - all subjects accounted for*</p> <p>b) Subjects lost to follow up unlikely to introduce bias - small number lost-&gt;____ % (select an adequate %) follow up, or description provided of those lost)*</p> <p>c) Follow up rate &lt; ____% (select an adequate %) and no description of those lost</p> <p>d) No statement</p>	<p>a) Were all cases accounted for at the end of the study period?</p> <p>*All cases which should be accounted for. In case of a recurrent event or death, this should be clearly reported.</p> <p>b) If the cases are lost due to other motives like a personal choice to leave the study or lack of information (e.g., no exposure information) in a certain period of the follow up in case of databases, the possible impact should be reported and how it influences in the analysis.</p> <p>c) the follow up rate should be stated</p>	<p>A study gets a star if it meets the requirements for item a or b</p>
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**Table 1:** The proposed quality assessment tool for the evaluation of the methodological quality of studies with a self-controlled case series and self-controlled risk interval designs

## Discussion

There are different quality evaluation tools for both quantitative and qualitative studies. At times, researchers modify existing tools or develop their own to meet their needs and this was our case. In 2018, we had to evaluate SCCS and SCRI included in a systematic review, and we couldn't find an existing tool that could be used. This led us to adapting the NOS for cohort studies.

This is the first version of the proposed quality assessment tool for SCCS and SCRI. It has been used in five studies: one master's degree dissertation, one published article, two projects of a scientific initiation program (not published), one thesis and one article submitted for publication [20-23]. It is based on the NOS that has never been published in a journal, thus has not undergone peer review. On the other hand, it is worth noting that the instrument was elaborated via Delphi method, has been tested in many systematic reviews and has been modified over this process [25]. Besides the critics the NOS receive, it has been used to evaluate innumerous studies included in published systematic reviews, thus confirming its validity and applicability.

In this first version of the tool, quality scores are recommended but no weighting scores have been attributed to the individual items in the domains evaluated. This allows flexibility of the evaluation process depending on the type of evidence synthesis being elaborated. Quality scores have previously been criticized as being poor predictors of the overall quality of a study especially when they are considered as a factor for the performance of a meta-analysis [26,27].

The SCCS and SCRI study designs are used in pharmacovigilance and are useful in analyzing rare events. They have been commonly used in studying populations after vaccine exposure like in the case of influenza vaccines and Human Papillomavirus vaccines [28,29]. Since 2020, the world has been facing the COVID-19 pandemic and in 2021, COVID-19 vaccines started being administered in all parts of the world. There has been temporal association of the COVID-19 vaccines or SARS-CoV-2 infection with the development of events like GBS, cardiovascular events like stroke, encephalitis, psychiatric events among others [30-32]. A huge number of both primary and secondary studies have been produced to report these events. The SCCS and SCRI could also be used in such cases and the use of the proposed quality assessment tool would be useful in ascertaining that the methodological rigor was adhered to, thus making the findings more reliable.

This proposed quality assessment tool has been used in a few studies,

some of which have been published or are undergoing peer review. It is worth highlighting that this is just an adaptation based on necessities that arose to evaluate self-controlled study designs. In the course of time, it will be subjected to a Delphi process to validate its use and enhance its applicability. It is our expectation that the tool will contribute to critical assessment of the methodological quality of SCCS and SCRI studies and that it will be continuously improved and adapted by the scientific community.

## Conclusion

The SCCS and SCRI are important study designs in pharmacoepidemiology and are useful in studying rare events reported after transient exposures, a good example are the influenza vaccines and the development of GBS. This paper presents a first proposal of a quality assessment tool for such studies. This came after the author's necessity to evaluate the methodological quality of such designs a few years back and no instrument was found, thus, the authors adapted an already existing tool and took into consideration the premises of SCCS/SCRI to design the tool. It is expected that the tool may guide researchers in assessing the methodological rigor of SCCS/SCRI study designs especially now with the COVID-19 pandemic where these designs could be widely used especially in studying the events being reported after the administration of the COVID-19 vaccines.

## Author Contributions

Wachira V.K: Conceptualization, Investigation, Methodology, Visualization, Writing Original Draft, Writing-review Peixoto H.M: Conceptualization, Supervision, Validation, Visualization, Writing-review De Oliveira M.R.F: Conceptualization, Supervision, Validation, Visualization, Writing-review.

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## Conflict of Interest

The authors do not have no conflicts of interest to declare that are relevant to the content of this article.

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