



Association between social determinants and Antimicrobial Resistance in *Neisseria gonorrhoeae*: A systematic review protocol

Registration: In accordance with the guidelines, our systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on March 07, 2021 (registration number CRD42021235168). The last update was on June 22, 2021.

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Contributions: JCR and DZ conceptualized the study and research question of the review. DZ, DR, and MS developed the search strategy, defined the data extraction criteria and degree of evidence quality assessment. DZ created the first draft of the systematic review protocol. MS and DR adjustment to the draft. All authors provided comments and adjustments, reviewed and approved the final version of the protocol.

Amendments: This protocol presents amendments made on 09 June, in the introduction, objectives, methods and, data results, and risk bias section.

Support: The research was supported by Asociacion Profamilia and financed by the UNICEF / UNDP / World Bank / WHO Special Program for Research and Training in Tropical Diseases (TDR).

Introduction

Chlamydia, gonorrhoeae, and syphilis are bacterial infections that are usually treated with antibiotics. In 2016, the World Health Organization (WHO) issued new therapeutic guidelines for these three sexually transmitted infections (STIs) to address antibiotic resistance as a growing threat. However, these STIs often go undiagnosed, and it is becoming increasingly difficult to treat them because some antibiotics are losing efficacy, which is commonly known as Antimicrobial resistance (AMR) (1,2).

AMR in STIs has a negative impact on morbidity, sexual and reproductive health of men and women, and fertility (3,4). Despite this, AMR occurs naturally over time, usually through genetic changes (5). However, this resistance is also caused by several factors, including unrestricted access to

antimicrobials, inappropriate selection and overuse of antibiotics, and poor-quality antibiotics (6). As a result of this misuse, AMR has been accelerating and thus therapeutic options are being reduced, which results in substantial economic cost worldwide; as this is not just a problem of the poor, and failures have also been observed in higher-income countries (5,6).

Previous research has addressed correlations of social determinants with antimicrobial resistance (7,8). In the model of social determinants of health proposed by the WHO, there are dimensions under which the different factors that determine health inequalities are grouped. At the structural level, the main determinants are education, income, social policies, area of residence, among others. At the intermediate level, determinants such as health services, access to sexual and reproductive health information, and communication play an important role. And at the individual level, high-risk behaviors, self-awareness, and individual choices may contribute to AMR in STIs (9,10).

N. gonorrhoeae can be prevented through safe sexual behavior, particularly consistent and correct use of condoms. In addition, information, education, and communication can promote and enable safer sex practices, improve people's ability to recognize the symptoms of gonorrhea and other STIs, and increase the likelihood of seeking care (11). Despite this, although there are studies on the role of social determinants in antimicrobial resistance to STIs, evidence continues to be limited and few studies have focused on explaining the correlation of social determinants (7,8,12–14)

In 2017, research on antimicrobial resistance was conducted in which *Neisseria gonorrhoeae* and *Mycoplasma genitalium* were studied. This study found that uncontrolled and excessive use of antimicrobial agents, limited AMR surveillance, and clinical failures tend to cause a higher prevalence of resistance and hinder patient management (12). In 2014, a study in Shanghai showed how education levels, income level, antibiotic misuse, and drug or alcohol use are determinants of resistance in different treatments against *N. gonorrhoeae* (13). In 2020, a study provided evidence on the social factors that explain inequalities in antimicrobial resistance to *N. gonorrhoeae* in Colombia. In general, evidence has shown that the main factors contributing to AMR are barriers to access to health services, lack of preventive information on STIs, unmet basic needs, and illiteracy (14).

Despite there being studies on the role of social determinants and in AMR to STIs, the evidence continues to be limited. Before carrying out this protocol, an exploratory search was conducted in scientific journals such as PubMed and Google Scholar. Through this, we sought to verify whether there were other systematic reviews on the role of social determinants in AMR to STIs, specifically *N. gonorrhoeae*. However, this systematic review may be the first review to evaluate this issue.

Based on the evidence found, there is wide variation in design, methodology, and reporting that limits the generalizability and applicability of these results. Therefore, this systematic review aims to investigate the role of social determinants of health and its relationship with AMR in *N. gonorrhoeae*.

Research question

This protocol addresses the following research question: Is antimicrobial resistance in *Neisseria gonorrhoeae* associated with social determinants of health?

Objectives

This review aims to describe and analyze the available evidence on the association between social determinants of health and antimicrobial resistance in *Neisseria gonorrhoeae*.

The specific aims are described as follows:

1. Identify published studies examining associations between at least one social determinant factor and antimicrobial resistance to *N. gonorrhoeae*, as a health outcome.
2. Analyze evidence from select studies to form a subgroup analysis given social determinant identified.
3. Assess the effects of social determinants on antimicrobial resistance in *Neisseria gonorrhoeae*.
4. Appraise all eligible studies' risk of bias using a validated risk of bias assessment tool.

Methods

This protocol for a systematic review of this literature adheres to the Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocol (PRISMA-P) (15) and the PRISMA Statement (16) to ensure that both (protocol and systematic review) are transparent and reproducible reporting search methods and information sources. This protocol was registered in PROSPERO.

Eligibility criteria

The following inclusion criteria items will be applied and based on previous systematic reviews.

The PICO method for constructing the question for socioeconomic status on antimicrobial resistance to *Neisseria gonorrhoeae* will be:

- Population: Population with a positive diagnosis, confirmed by laboratory studies, for *Neisseria gonorrhoeae* older than 12 years.
- Interventions: This review will focus on studies that report on Social Determinants of Health (SDH) as measured by poverty, education, income, area of residence, ethnicity; health services; risk factors, practices, and behaviors.
- Comparison: the best-off social groups or those with higher social position according to the selected social determinant of health.
- Outcomes: antimicrobial resistance to *Neisseria gonorrhoeae*.

Types of study

This systematic review will focus on the following two types of studies: all types of experimental and non-experimental epidemiological studies. For instance, observational studies (cohort, multi-cohorts, cross-sectional, case-control) with correlations, univariate and multivariate analyses, explanatory models of health determinants based on regressions, multivariate analysis, predictive models in machine learning performed will be relevant. Similarly, studies where inequalities are measured, either as a comparison between groups, in two or more groups, variance, variation coefficient, using the concentration index, relative risk, slope inequality index, and other indexes that focus on the purpose of the review. Also, randomized controlled trials and quasi-experimental studies such as interrupted time series, instrumental variables, difference-in-differences, regression discontinuity design, and panel analysis if fixed-effects).

Participants/population

This review will include experimental and non-experimental epidemiological studies with a population with positive diagnosis, confirmed by laboratory studies, for *Neisseria gonorrhoeae*. Evidence has shown that behaviors during adolescence are linked with the development of drug resistance. Therefore, participants from 12 years old will be included in this revision.

Intervention(s), exposure(s)

This review will focus on studies that report Social Determinants of Health (SDH). According to the model of SDH proposed by the WHO, there are dimensions under which the different factors that determine health inequalities are grouped. The first, structural determinants, are those that generate social stratification and include socioeconomic status, measured through socio-demographic variables; territory, and ethnicity. The second, intermediate determinants, which flow from the configuration of being below social stratification and determine the differences in health exposure and vulnerability. The third, individual determinants, which are factors flowing from individual lifestyles, risk factors, psychosocial factors, and behavioral factors. Through these determinants, it is possible to identify how social inequalities are related to the development of AMR.

Condition or domain being studied

At least one of the following SDH, associated with AMR to *Neisseria gonorrhoeae*.

Structural determinants, which include (9):

- Level of education: indicators or rates of illiteracy, literacy, schooling, academic achievement, or schooling coverage.
- Poverty: poverty rate, multidimensional poverty index, the incidence of poverty, extreme poverty, wealth index, or unmet needs indicators.
- Employment: employment rate, unemployment rate, or economically active population indicators.
- Ethnic or racial origin: percentage or rate of people who belong to ethnic minorities.
- Area of residence: percentage of people living in urban, rural, or insular areas.
- Housing conditions: housing quality indexes, access to sanitary services, water coverage percentage, or drinking water index.

Intermediate determinants, which include (9):

- Access to healthcare services: percentage of people receiving care, percentage of people with access barriers to healthcare services, healthcare quality, treatment access, use of medications, and clinical failures.
- Access to quality information in health services: number of people or percentages of people who got talks, counseling on the use of methods and medications, percentage of people who receive promotional, preventive, and early detection messages.

Individual-level determinants, which include: age, sex, group of risk, comorbidity, or behavioral factors (unsafe sex, smoking, drug use, or alcoholism) (9).

Comparator or Control

According to the interventions, the comparison groups will be the best-off social groups or those with higher social position according to the selected social determinants of health.

Context

No geographical location restrictions. Therefore, studies at the individual and area/context (local, national, regional, multinational) level evaluating the association between social determinants and antimicrobial resistance in *Neisseria gonorrhoeae* will be included.

Publication status

We will focus on peer-reviewed articles, master's or doctoral theses, and grey literature, published in full text. Studies published in English or Spanish, in a period between 2010 and 2020.

On the other hand, studies that do not address any of the social determinants of interest, qualitative studies on antimicrobial resistance in *Neisseria gonorrhoeae*, or resistance studies in agriculture and animals will also be excluded. Finally, studies with a specific clinical focus, studies focused on microbiology, and studies that do not include resistance in humans will be excluded.

Main outcomes

Studies focused on antimicrobial resistance to *Neisseria gonorrhoeae* (Gonorrhoea) associated with at least one social determinants of health.

Additional outcomes

The secondary outcome will be studies linking coinfection between STIs such as the *Human Immunodeficiency Virus (HIV)*, *Mycoplasma genitalium*, *Chlamydia trachomatis* or *Treponema pallidum* and *Neisseria gonorrhoeae*, associated with antimicrobial resistance or treatment failure.

Measures of effect

Age and gender will be considered as possible modifiers of antimicrobial resistance, absolute risks, relative risks, odds ratios, hazard ratios, or rate of people with drug resistance explained by social determinants.

Information Sources

This systematic intend to use the following electronic databases covering the period 2010-2020:

- PubMed
- Web of Science
- Cochrane Public Health Group Specialized Register
- Cochrane Central Register of Controlled Trials
- Plos Journals
- Ovid databases (Embase)
- Grey literature

Search Strategy

This systematic review will have a search strategy based on 4 search equations (2 in English and 2 in Spanish) taking into account the characteristics of each search engine using the following keywords from the thesaurus of Health Sciences Descriptors, DeCS.

STI

Sexually Transmitted Diseases (STI)
Chlamydia

Enfermedades de Transmisión Sexual (ITS)
Clamidia

Syphilis	Sífilis
<i>Neisseria gonorrhoeae</i>	<i>Neisseria gonorrhoeae</i>
Gonorrhea	Gonorrea
Gonococcus	Gonococo
Gonococci	Gonocócica
<i>Neisseria gonorrhoeae</i> bacterium	Bacteria <i>Neisseria gonorrhoeae</i>
<i>Neisseria gonorrhoeae</i> infections	Infecciones por <i>Neisseria gonorrhoeae</i>
Antimicrobial resistance	
Antimicrobial resistance	Resistencia Antimicrobiana
Antibiotic resistance	Resistencia a antibióticos
Drug Resistance	Resistencia a Medicamentos
Drug Resistance, Microbial	Farmacorresistencia Microbiana
Socioeconomic status	
Social factors	Factores sociales
Social conditions	Condicionales sociales
Socioeconomic factors	Factores Socioeconómicos
Socioeconomic status	Estatus socioeconómico
Health Services Accessibility	Accesibilidad a los Servicios de Salud
Social determinants of health	Determinantes sociales de la salud

This search strategy will adapt appropriately to the requirements of each database. However, sometimes we will have to formulate things slightly differently (e.g., the use of quotation marks in the search in Spanish).

First, we developed the PubMed search strategy. We received librarian professional advice for the development of the search strategy and the management of the search engine.

PubMed database

- Use Boolean operators: "OR" to gather synonyms referring to key concepts and "AND" separate search groups.
- Use field tags: All fields.
- Use of quotation marks to find results in Spanish search equations.
- Use parentheses with the following queries, both, in English and Spanish.

The keywords described will be applied to reach a wide range of publications:

English:

- (antimicrobial resistance OR antibiotic resistance OR drug Resistance OR drug Resistance, Microbial) AND (Sexually transmitted infections OR chlamydia OR syphilis OR *Neisseria gonorrhoeae* OR gonococcus OR gonococci OR gonorrhea OR *Neisseria gonorrhoeae* bacterium OR *Neisseria gonorrhoeae* infections) AND (social factors OR social conditions OR Socioeconomic status OR Socioeconomic factors OR Social determinants of health)

- (antimicrobial resistance OR antibiotic Resistance OR drug resistance, microbial) AND (*Neisseria gonorrhoeae* OR gonococcus OR gonococci OR Gonorrhoea OR *Neisseria gonorrhoeae* bacterium OR *Neisseria gonorrhoeae* infections) AND (Socioeconomic factors OR Social Determinant of health OR Health Services Accessibility)

Spanish:

- ("resistencia antimicrobiana" OR "resistencia a medicamentos" OR "farmacorresistencia Microbiana") AND ("infecciones de transmisión sexual" OR "clamidia" OR "sífilis" OR "*Neisseria gonorrhoeae*" OR "gonorrea" OR "gonocócica" OR "gonococo" OR "bacteria *Neisseria gonorrhoeae*" OR "infecciones por *Neisseria gonorrhoeae*") AND ("factores sociales" OR "condiciones sociales" OR "factores socioeconómicos" OR "determinantes sociales de la salud" OR "accesibilidad a servicios de salud")
- ("resistencia antimicrobiana" OR "resistencia a medicamentos" OR "farmacorresistencia Microbiana") AND ("*Neisseria gonorrhoeae*" OR "Gonorrea" OR "Gonococo" OR "gonocócica" OR "bacteria *Neisseria gonorrhoeae*" OR "infecciones por *Neisseria gonorrhoeae*") AND ("factores socioeconómicos" OR "determinantes sociales de la salud" OR "accesibilidad a servicios de salud")

Limiters:

- Publication date from 2010 to 2020.
- Language, English, or Spanish.
- Type of access: abstract and Free full-text.
- Specie: excluded animals and agriculture studies.
- Type of studies: excluded qualitative studies, clinical studies.

Cochrane Library

- Use field tags: title, abstract, keyword.
- Do not use quotation marks to find results in Spanish search equations.
 - Eg. (resistencia antimicrobiana AND *Neisseria gonorrhoeae* AND factores socioeconómicos)

Limiters:

- Publication date from 2010 to 2020.
- Language, English, or Spanish.

Web of science

- Use field tags, Boolean operators, parentheses, and query sets to create a query.
 - E.g. query sets:
 - #1: ALL= (Drug resistance OR antimicrobial resistance)
 - #2: ALL= (*Neisseria gonorrhoeae* OR gonococci)
 - #3: ALL= (Socioeconomic status OR social conditions)
 - Combined query: #1 AND #2 AND #3
- Use of quotation marks to find results in Spanish search equations.

Limiters:

- Publication years from 2010 to 2020.
- Language, English, or Spanish.
- Type of access: open access.

Plos Journals

- Use field tags, Boolean operators, parentheses.
- Type of access is Free full-text.

Limiters:

- Publication date from 2010 to 2020.

Ovid databases (Embase)

- Separate search strategy with keywords by query sets to create a final query.
- Use Boolean operators.
 - E.g. query sets:
 - #1: “STI” keywords using Boolean OR
 - *Neisseria gonorrhoeae*
 - Gonococci
 - #2: “Antimicrobial resistance” keywords using Boolean OR
 - Drug resistance
 - Antimicrobial resistance
 - #2: “Socioeconomic status keywords” using Boolean OR
 - Socioeconomic status
 - Social conditions
 - Combined Query: #1 AND #2 AND #3

Limiters:

- Publication date from 2010 to 2020.

Grey Literature

Grey literature databases include:

- OpenGrey.eu: It is a European grey literature database covering all subject area;
- OpenAIRE.eu: It is an Open Access Infrastructure for research, based on the network of open access repositories;
- Institutional Repository for Information Sharing (IRIS): IRIS is the World Health Organization’s Institutional Repository;
- Repositorio Institucional Digital (RID): RID is the Colombian Ministry of Health and Social Protection’s Institutional Repository.

A record of the searches will be kept in each database in an Excel matrix. After developing the search strategy in each database, duplicates will be eliminated and the resulting studies will be included in the review of titles and abstracts.

Study Records

Data Management

The articles selected, both included and excluded, will be included in Mendeley Reference Manager, a free web and desktop reference management application. Multiple Excel tables will also be created to support the analysis and record important information.

Selection process

Two reviewers (DZ and DR) will revise search strategies for each database, both reviewers will search for the results and compare the number of retrieved studies. If identical, one reviewer (DZ) will use Mendeley to remove all duplicates. One reviewer (DZ) will screen all studies by titles and abstracts, applying all the inclusion criteria. If an abstract does not have sufficient information or is not available, the full text will be reviewed in sessions of 15 to 20 min. The screen full-text aims to identify relevant studies that address the research question. A second reviewer (DR) will validate this process to ensure that the selected studies meet the criteria. In case of disparities in the results, a third reviewer (MS) will decide. Once the abstracts have been selected, full-text will be reviewed, verifying that the information included fully meets all the inclusion criteria. The articles selected in this step will finally be included in the systematic review.

Data Extraction

Data extraction will be carried out by the author of the systematic review (DZ). The main health outcome of this review is antimicrobial resistance in *Neisseria gonorrhoeae*, whose social determinants explain this resistance. An additional outcome of this review is the coinfection between STIs such as the *Human Immunodeficiency Virus (HIV)*, *Mycoplasma genitalium*, *Chlamydia trachomatis* or *Treponema pallidum* and *Neisseria gonorrhoeae*, associated with antimicrobial resistance or treatment failure. Both outcomes can be measured through absolute risks, relative risks, odds ratios, hazard ratios, or the rate of people with drug resistance explained by social determinants.

The information will be recorded in an Excel table, including information such as title, author(s), country or countries, year of publication, sample size, descriptions of social determinants, health outcome, relative measures (OR, HR, CI, inequality indexes) and method to control bias. In this way, this compilation will support the analysis of results, as well as the evaluation of the risk of bias and the quality of the studies.

Data Results and Analysis

This systematic review will synthesize the findings based on population details, SES description, comparator type, outcome, and study design. The studies with selected socioeconomic status measures will be analyzed by risk ratios to measure effects for dichotomous and ordinal outcomes in studies with separate control groups. If risk ratios are not provided but can be calculated based on the available data, we will calculate risk ratios or contact the corresponding author to calculate risk ratios that are not available to obtain such data. If we cannot obtain or calculate the risk ratio, we will report the study's effect. We will use this information to reflect on similarity, data availability, and feasibility to conduct a meta-analysis (if studies are sufficiently homogenous in terms of predictors and outcomes measures reported). These analyses will be presented in a summarized and organized way (by tables or maps) evidencing the outcomes of each study.

Risk of bias (quality) assessment

We will use the latest version of Cochrane Collaboration's RoB Tool to assess the risk of bias in experimental studies each study. This tool provides a model to evaluate the risk of bias tool across six domains of bias: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. Each domain for each study will be allocated a ranking of "low", "unclear", or "high" risk of bias, in accordance with the Cochrane Collaboration's approach (17).

To assess the risk of bias in non-experimental or observational studies, the methodological quality of potential studies will be assessed by using the Newcastle-Ottawa scale (NOS) (18). Using the NOS, studies will be awarded a maximum of nine points on items related to the selection of the study groups, the comparability of the groups, and the ascertainment of outcome of interest, and studies with more than seven points are low-risk studies. Two reviewers (DZ and DR) will each independently evaluate the risk of biases, and any disagreement will be resolved by consulting with the supervision team.

Confidence in cumulative evidence

This review will assess the evidence strength by rating four components of the methodology of each study, including study design, sample size, covariates, and used measures of inequality. The assessment will take into account four criteria:

1. Show representativeness: studies where the sample design and size are indicated to guarantee representativeness and in which sampling errors are minimal and where sample selection is carried out using probabilistic methods. Studies based on total population data (population censuses) or administrative records (health care, for example).
2. Studies where the health outcome (AMR in STIs or specifically in *Neisseria gonorrhoeae*) is measured via disaggregated data at the individual level rather than at an area or contextual level. For example, studies that use anonymous data at the individual level rather than aggregated data (municipalities, township, departments, region, country).
3. Analyses that account for/control for bias and confounding factors.
4. Whether the study is completely focused on *Neisseria gonorrhoeae* resistance.

Evidence level assessment will award one (1) point maximum for each criterion. Besides, an additional award for the first criterion will be awarded from one (1) point for studies with a sample size between 500-1000 or two (2) points for studies with a sample size above 1,000. Studies may obtain a minimum of zero points and a maximum of six points. Studies rated between 0-2 points will be grouped as low quality, 3 points as medium quality, and 4-6 points as high quality.

Ethics and Dissemination

As this review will use published data, ethical approval is not required. Dissemination in open access, a peer-reviewed international scientific journal is planned. Given the importance of antimicrobial resistance as a global health threat, this information may contribute to an evidence-based study on socioeconomic conditions and social inequality dimensions that influence resistance to *Neisseria gonorrhoeae*.

Conflicts of Interest:

No conflicts of interest are declared.

Type and method of review

Systematic review

Anticipated or actual start date

17 February 2021

Anticipated completion date

25 June 2021

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