

A Multi-component Intervention to Reduce Gaps in Hypertension Care and Control in Medellin, Colombia

INFORMED CONSENTS V.2.0.
dated: 29-Apr-2019

Reducing gaps in hypertension care and control in Colombia

Annex 10. Informed consent for endline survey

Study title: Gaps in hypertension care and control in Medellín, Colombia: cross-sectional survey in two Communes.

Principal Investigator: Dr. Esteban Londoño Agudelo, MD. MPH. **Institution:** ITM, Belgium – University of Antioquia, Colombia.

Metrosalud E.S.E. (Medellín, Colombia), the University of Antioquia (Medellín, Colombia) and the Institute of Tropical Medicine (Antwerp, Belgium) are conducting a study on the gaps in the process of care and control of hypertension at population level in Medellín city, Colombia.

This informed consent form has two parts:

Part I: Information sheet (to share information about the study with you)

Part II: Signature of Consent (for signature if you choose to participate)

You will be given a copy of both parts.

Part I: Information sheet

Introduction: We invite you to participate in this research study on how to improve the medical care and treatment for high blood pressure in the city. It is important that you understand the information given in this sheet before you decide to be part of this study. This sheet explains your rights and our responsibilities to you. We are going to give you information on the study and invite you to be part of this research. This sheet is asking for your consent. It may contain words that you do not understand, so please feel free to ask any question regarding this study before you decide to participate. If you have questions later, you can ask them to the study responsible, **Dr. Esteban Londoño** or to any member of the team. You can also go directly to the Direction of the Hospital of Metrosalud in Santa Cruz, asking for Dr. Hernán Aguilar; or to the Direction of the Hospital of Metrosalud in Doce de Octubre, asking for Dr. Valentina Sossa.

Purpose and description of the research:

People with high blood pressure readings (that is, hypertension), who are still not detected or not properly treated by a doctor can suffer from serious health problems. Uncontrolled high blood pressure can lead to serious problems like heart attacks, strokes, heart failures, and renal failures. If a community has a lot of people with uncontrolled high blood pressure, we can expect to find a lot of individuals suffering from serious health problems or prematurely dying. We want to find out how many people have high blood pressure readings among individuals 35 years or older in your Commune and what are the main problems that prevent the health personnel to detect people suffering from high blood pressure and to properly treat them. The results of this study can help to detect the main problems for the people of this Commune to receive timely and good health care for high blood pressure. We will use the results of this research to design strategies to improve the quality of health care for people living with high blood pressure.

Participants selection: People aged 35 years or older who live in the Commune can join this study. Using a computerized program, we have randomly selected a group of homes in each neighborhood, which will take part in this study. Then, in each selected home we will interview all the inhabitants aged 35 years or older.

Voluntary participation: Your decision to join this study is totally voluntary. It is your choice whether to participate or not. On the other hand, if you decide to join, you can choose to answer only the questions that you like. You can also leave the study at any time, even after you have signed this Informed Consent Form.

Procedures: Using a questionnaire, we will ask questions about your health, how often you use health services, what are your health problems and general health. We will especially ask you if you suffer from high blood pressure. In case you do, we will ask you about your treatment and how often you get follow-up consultations. This won't take much time, approximately 60 minutes, a professional survey taker for this study, will carry out the interview. The survey taker will also measure your blood pressure readings three times during the interview.

Risks and discomforts: There is no physical risk. You will only share personal information and if you feel any question too personal or you feel uncomfortable you do not have to answer. The study will not interfere with the health care that you receive.

Benefits: You will not receive direct benefits from this study, neither incentives to participate. With no doubt you will

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obtain more information on what high blood pressure is, what are the measures you can take to prevent the disease and also how to get medical control. If during the interview the survey taker finds out that you have high blood pressure or any medical complication, you will be informed and referred to the health center where you are subscribed. Furthermore, the results of this study can help to improve how to provide health care to people with high blood pressure in Medellin and in Colombia.

Confidentiality: The information that you provide us will be kept confidential and will be accessed only by the study investigators. All formats in the study will be recognized by a number code, not by your name. Your name or any data that could identify you will not be revealed by the research team. Your identity will never be revealed in any report or publication resulting from this study.

Sharing the results: The results of this study will be shared with the managers of Metrosalud E.S.E. and of the health insurance companies of the Contributory Regimen; and may be published in national and or international scientific journals.

Right to Refuse or Withdraw from the study: The participation in this study is voluntary and you are not obliged to participate. If you prefer not to participate this won't influence the medical care and treatment that you receive. You can withdraw from the study at any time. You can refuse to answer any question that you feel uncomfortable. Should you have any question on the study, you can ask all questions that you want, either now or at any other time. In this case you can contact the principal investigator of this study, *Dr. Esteban Londoño Agudelo* (see below).

*Reducing gaps in hypertension care and control in Colombia***Part II: Signature of the consent.****Part for the participant**

I declare that I have been informed about this study and that I have received a copy of the Informed Consent. I have been explained and read the information and I understand the objectives and procedures of the study, and that the collected data will be used only for this investigation. I had the chance to ask questions on the study and clarify doubts.

I freely consent to participate in this study and understand that I have the right to withdraw from the study at any time, without any consequence for me.

In consideration of the above, I sign this document on

Date: day ____ month ____ year ____

Name and surnames of the participant

Signature: _____

Part for the investigator: I duly read the informed consent form to the potential participant, and the person had the opportunity to ask questions. I confirm that the person has given his/her consent voluntarily.

Date: day ____ month ____ year ____

Name and surnames of the Investigator: _____

Signature:

Any question on the study can be addressed to the study responsible: **Dr. Esteban Londoño Agudelo**,
Facultad Nacional de Salud Pública, Universidad de Antioquia. Calle 62 No. 52-59. Phone: +57(4) 2196822,
email: estebanlondonoag@gmail.com

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Part for the participant I declare that I have been informed about this study and that I have received a copy of the Informed Consent. I have been explained and read the information and I understand the objectives and procedures of the study, and that the collected data will be used only for this investigation. I had the chance to ask questions on the study and clarify doubts.

I freely consent to participate in this study and understand that I have the right to withdraw from the study at any time, without any consequence for me.

In consideration of the above, I sign this document on

Date: day ____ month ____ year ____

Name and surnames of the participant

Signature _____

Part for the investigator: I duly read the informed consent form to the potential participant, and the person had the opportunity to ask questions. I confirm that the person has given his/her consent voluntarily

Date: day ____ month ____ year ____

Signature:

Name and surnames of the Investigator: _____

Reducing gaps in hypertension care and control in Colombia

Study title: “A multi-component intervention to reduce gaps in hypertension care and control in Medellin, Colombia”

(Qualitative data collection of process evaluation in the intervention commune).

Principal Investigator: Dr. Esteban Londoño Agudelo, MD. MPH.

Institution: ITM, Belgium – University of Antioquia, Colombia.

Metrosalud E.S.E. (Medellin, Colombia), the University of Antioquia (Medellin, Colombia) and the Institute of Tropical Medicine (Antwerp, Belgium) are conducting a study on the gaps in the process of care and control of hypertension at population level in Medellin city, Colombia.

This informed consent form has two parts:

Part I: Information sheet (to share information about the study with you)

Part II: Signature of Consent (for signature if you choose to participate)

You will be given a copy of both parts.

Part I: Information sheet

Introduction: We invite you to participate in this research study on the improvement of hypertension care and control in the Commune. It is important that you understand the information given in this sheet before you decide to be part of this study. This sheet explains your rights and our responsibilities to you. We are going to give you information on the study and invite you to be part of this research. This sheet is asking for your consent. It may contain words that you do not understand, so please feel free to ask any question regarding this study before you decide to participate. If you have questions later, you can ask them to the study responsible, **Dr. Esteban Londoño** or to any member of the team. You can also go directly to the Direction of the Hospital Unit of Metrosalud in Santa Cruz, asking for Dr. Hernán Aguilar.

Purpose and description of the research:

People with hypertension, who are still not detected or not properly treated can suffer from serious health problems. Uncontrolled high blood pressure can lead to serious problems like heart attacks, strokes, heart failures, and renal failures. If a community has a lot of people with uncontrolled high blood pressure, we can expect to find a lot of young people (under 70 years of age) suffering from serious health problems or prematurely dying. We want to contribute to address the main problems that prevent the timely detection and adequate treatment of people with hypertension in the Commune. To achieve this, we have implemented a number of improvement interventions in the Commune's Metrosalud health services and in the community. For this purpose, a few months ago, you were explained about the intervention activities and invited to implement them. You were provided with the skills, guidelines and all the resources required to improve hypertension care and control actions within your health service. As part of the study, we are going to monitor and evaluate the implementation of the activities assigned to you and the rest of the involved health workers. We will use the results of this research to identify the main difficulties and to improve the implementation of the different components of the intervention. The results of this study can contribute to improve the quality of the health care provided to people living with hypertension.

Participants selection: Health providers involved in implementation of the different components of the intervention to improve hypertension care and control in the intervention commune.

Annex 11. Informed Consent for semi-structured interviews on health providers. Version 2.0, dated 18-APR-2019

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Voluntary participation: Your decision to join this study is totally voluntary. It is your choice whether to participate or not. On the other hand, if you decide to join, you can choose to answer only the questions that you like. You can also leave the study at any time, even after you have signed this Informed Consent Form.

Procedures: If you agree to participate in the research, you could be subject of observation of your activities and semi-structured interviews. Observations will be conducted by research staff (“observers”) in a systematic way and at different points in time. The exact moment of the observation will not be communicated not to interfere with your activities and not to influence or bias your performance. The observer will take notes of the activities you conduct as part of the intervention. Based on those notes you could be further interviewed by the research staff. The time and the place of the interview will be arranged with you in advance. The interview could take between 45 minutes and one hour. The interviewer will ask you some questions. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. We foresee to tape-record the entire interview unless you do not allow us doing so. Your name will not be identified on the tape. The recorded information will be confidential and the tapes will be destroyed after three months.

Risks and discomforts: The risks related to observation and interview are minimal. There is no physical risk. You will only share personal information and if you feel any question too personal or you feel uncomfortable you do not have to answer. The study will not represent an evaluation or report of your performance.

Benefits: You will not receive direct benefits from this study, neither incentives to participate. The results of this study can help to improve how to provide health care to people with hypertension in Medellin and in Colombia.

Confidentiality: The information that you provide us will be kept confidential and will be accessed only by the study investigators. All formats of the study will be recognized by a number code, not by your name. Your name or any data that could identify you will not be revealed by the research team. Your identity will never be revealed in any report or publication resulting from this study.

Sharing the results: The results of this study will be shared with the managers of Metrosalud E.S.E. and of the health insurance companies of the Contributory Regimen; and may be published in national and or international scientific journals.

Right to Refuse or Withdraw from the study: The participation in this study is voluntary and you are not obliged to participate. If you prefer not to participate this won’t have any implication for your job or work-related evaluation. You can withdraw from the study at any time. You can refuse to answer any question that you feel uncomfortable. You can also stop the interview at any time if you decide to do so.

Should you have any question on the study, you can ask all questions that you want, either now or at any other time. In this case you can contact the principal investigator of this study, *Dr. Esteban Londoño Agudelo* (see below).

Annex 11. Informed Consent for semi-structured interviews on health providers. Version 2.0, dated 18-APR-2019

*Reducing gaps in hypertension care and control in Colombia***Part II: Signature of the consent.****Part for the participant**

I declare that I have been informed about this study and that I have received a copy of the Informed Consent. I have been explained and read the information and I understand the objectives and procedures of the study, and that the collected data will be used only for this investigation. I had the chance to ask questions on the study and clarify doubts.

I freely consent to participate in this study and understand that I have the right to withdraw from the study at any time, without any consequence for me.

I agree that the interview can be recorded: Yes No

In consideration of the above, I sign this document on **Date:** day ____ month ____ year ____

Name and surnames of the participant

Signature: _____

Part for the investigator: I duly read the informed consent form to the potential participant, and the person had the opportunity to ask questions. I confirm that the person has given his/her consent voluntarily.

Date: day ____ month ____ year ____

Signature:

Name and surnames of the Investigator: _____

Any question on the study can be addressed to the study responsible: **Dr. Esteban Londoño Agudelo, Facultad Nacional de Salud Pública, Universidad de Antioquia. Calle 62 No. 52-59. Phone: +57(4) 2196876, email: elondono@ext.itg.be**

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Part for the participant: I declare that I have been informed about this study and that I have received a copy of the Informed Consent. I have been explained and read the information and I understand the objectives and procedures of the study, and that the collected data will be used only for this investigation. I had the chance to ask questions on the study and clarify doubts.

I freely consent to participate in this study and understand that I have the right to withdraw from the study at any time, without any consequence for me.

I agree that the interview can be recorded: Yes No

In consideration of the above, I sign this document on **Date:** day ____ month ____ year ____

Name and surnames of the participant

Signature: _____

Part for the investigator: I duly read the informed consent form to the potential participant, and the person had the opportunity to ask questions. I confirm that the person has given his/her consent voluntarily

Date: day ____ month ____ year ____

Signature:

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Reducing gaps in hypertension care and control in Colombia

Study title: A multi-component intervention to reduce gaps in hypertension care and control in Medellin, Colombia

(Qualitative data collection of process evaluation in the intervention commune)

Principal Investigator: Dr. Esteban Londoño Agudelo, MD. MPH.

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You will be given a copy of both parts.

Part I: Information sheet

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Purpose and description of the research:

People with high blood pressure readings (that is, hypertension), who are still not detected or not properly treated can suffer from serious health problems. Uncontrolled high blood pressure can lead to serious problems like heart attacks, strokes, heart failures, and renal failures. If a community has a lot of people with uncontrolled high blood pressure, we can expect to find a lot of young people (under 70 years of age) suffering from serious health problems or prematurely dying. We want to contribute to solve the main problems that prevent the health personnel from detecting people suffering from high blood pressure and to properly treat them in your Commune. In order to do so, we have implemented a number of improvement interventions in the Commune's Metrosalud health services and in the community. The results of this study can help to improve the quality of the health care provided for people living with high blood pressure.

Annex 12. Informed consent for in-depth interview with patients, version 2.0, dated 18-APR-2019

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Participants selection: you have been selected to participate because you are aged 35 years or older and live in the Commune.

Voluntary participation: Your decision to join this study is totally voluntary. It is your choice whether to participate or not. On the other hand, if you decide to join, you can choose to answer only the questions that you like. You can also leave the study at any time, even after you have signed this Informed Consent Form.

Procedures: If you agree to participate in the research, we will conduct an in-depth interview with you, once you have signed this document. The interview could last for one or more sessions of about one hour each. During the first session, we will agree with you the most comfortable pace for you. If after the first session additional information is required we will ask you to arrange new sessions. In each interview session, the interviewer will ask you some questions on your knowledge, opinion and experience with hypertension and the health care you receive for it. If you do not wish to answer any of the questions, you may say so and the interviewer will move on to the next question. We foresee to tape-record the entire interview unless you do not allow us doing so. Your name will not be identified on the tape. The information recorded will be confidential and the tapes will be destroyed after three months.

Risks and discomforts: The risk related to the interview is minimal. There is no physical risk. You will only share personal information and if you feel any question too personal or you feel uncomfortable you do not have to answer. The study will not interfere with the health care that you receive.

Benefits: You will not receive direct benefits from this study, neither incentives to participate. With no doubt you will obtain more information on what high blood pressure is, what are the measures you can take to prevent the disease and also how to get medical care. The results of this study can help to improve how to provide health care to people with high blood pressure in Medellin and in Colombia.

Confidentiality: The information that you will provide us will be kept confidential and will be accessed only by the study investigators. All formats in the study will be identified by a code, not by your name. Your name or any data that could identify you will not be revealed by the research team. Your identity will never be revealed in any report or publication resulting from this study.

Sharing the results: The results of this study will be shared with the managers of Metrosalud E.S.E. and of the health insurance companies of the Contributory Regimen; and may be published in national and international scientific journals.

Right to Refuse or Withdraw from the study: The participation in this study is voluntary and you are not obliged to participate. If you prefer not to participate this won't influence the medical care and treatment that you receive. You can withdraw from the study at any time. You can refuse to answer any question that you feel uncomfortable. You can also stop the interview at any time if you decide to do so.

Annex 12. Informed consent for in-depth interview with patients, version 2.0, dated 18-APR-2019

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Should you have any question on the study, you can ask all questions that you want, either now or at any other time. In this case you can contact the principal investigator of this study, *Dr. Esteban Londoño Agudelo* (see below).

Annex 12. Informed consent for in-depth interview with patients, version 2.0, dated 18-APR-2019

*Reducing gaps in hypertension care and control in Colombia***Part II: Signature of the consent.****Part for the participant**

I declare that I have been informed about this study and that I have received a copy of the Informed Consent. I have been explained and read the information and I understand the objectives and procedures of the study, and that the collected data will be used only for this investigation. I had the chance to ask questions on the study and clarify doubts.

I freely consent to participate in this study and understand that I have the right to withdraw from the study at any time, without any consequence for me.

I agree that the interview can be recorded: Yes No

In consideration of the above, I sign this document on **Date:** day ____ month ____ year ____

Name and surnames of the participant

Signature: _____

Part for the investigator: I duly read the informed consent form to the potential participant, and the person had the opportunity to ask questions. I confirm that the person has given his/her consent voluntarily.

Name and surnames of the Investigator: _____

Date: day ____ month ____ year ____ **Signature:** _____

Any question on the study can be addressed to the study responsible: **Dr. Esteban Londoño Agudelo, Facultad Nacional de Salud Pública, Universidad de Antioquia. Calle 62 No. 52-59. Phone: +57(4) 2196876,**
email: elondono@ext.itg.be

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Part for the participant: I declare that I have been informed about this study and that I have received a copy of the Informed Consent. I have been explained and read the information and I understand the objectives and procedures of the study, and that the collected data will be used only for this investigation. I had the chance to ask questions on the study and clarify doubts.

I freely consent to participate in this study and understand that I have the right to withdraw from the study at any time, without any consequence for me.

I agree that the interview can be recorded: Yes No

In consideration of the above, I sign this document on **Date:** day ____ month ____ year ____ **Name and surnames of the participant**

Signature: _____

Part for the investigator: I duly read the informed consent form to the potential participant, and the person had the opportunity to ask questions. I confirm that the person has given his/her consent voluntarily

Name and surnames of the Investigator: _____

Date: day ____ month ____ year ____ **Signature:** _____

Annex 12. Informed consent for in-depth interview with patients, version 2.0, dated 18-APR-2019