Surveillance and Clinical Research of Diseases Caused by Immunization at Sulianti Saroso IDH, Jakarta

Vivi Lisdawati, MSi., Apt., PhD.
Director of Research
Sulianti Saroso IDH, DG of HS, MoH RoI
November 13, 2019
Tokyo, Japan
1. Sulianti Saroso Infectious Diseases Hospital

2. Surveillance of Diseases Caused by Immunization at Sulianti Saroso IDH

2b. Halal Certification for Drugs and Pharmaceutical Supplies in Indonesia

3. Clinical Research / Clinical Trial at Sulianti Saroso IDH

3b. Material Transfer Agreement (MTA) Regulation

4. Ministry of Health: Strategic Plans for 2020-2024
1. MEGA BIODIVERSITY
2. HOT SPOTS of ZOONOSIS
3. VARIOUS TROPICAL INFECTIOUS DISEASES
4. HIGH POPULATION
DISEASES OUTBREAKS 20..

Map identifies origin of diverse or serious outbreak spreading or flared-up recently
IHR (2005)

- Reducing the risk of disease circulation.
- Prevent, detect, assess, report and respond action.
Government (MoH)-owned Hospitals

33 HOSPITALS

Ministry of Health-Owned Hospitals

New general hospital development plan
100 GENERAL HOSPITAL OF INFECTIOUS DISEASES NETWORKS

561 Districts
ADRESS:
JL. BARU SUNTER PERMAI RAYA
North Jakarta. 14340.

Surface area
± 4 HA = 0.04 Km²

Building area
± 1.6HA = 0.016 Km²
Hospital Profile

- Technical Unit of the Ministry of Health, RoI.
- Specific Hospital for Infection Diseases, Class A Type with National Accreditation (SNARS ED.1)
- Teaching Hospital (AHS – UI)
- 156 beds

### ROOM TYPE | NUMBER
--- | ---
HCU | 7
VVIP | 2
VIP | 3
CLASS I | 26
CLASS II | 19
CLASS III | 72
PERINA | 5
MDR TB ISOLATION | 2
HIGH-RISK ISOLATION | 10
ICU HIGH RISK ISOLATION | 1
GENERAL ISOLATION | 4
**TOTAL** | **156**
## 10 Most Cases at Emergency Unit Year 2016 - 2018

<table>
<thead>
<tr>
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<th>No</th>
<th>Diseases</th>
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<th>Diseases</th>
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<td>5</td>
<td>Fever</td>
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<td>6</td>
<td>Dyspepsia</td>
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<td>Abdomen pain</td>
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</tr>
<tr>
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<td>8</td>
<td>HIV</td>
<td>8</td>
<td>ISPA</td>
</tr>
<tr>
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<td>9</td>
<td>ISPA</td>
<td>9</td>
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<td>10</td>
<td>Headache</td>
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<tr>
<td></td>
<td>2016</td>
<td>2017</td>
<td>2018</td>
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<td></td>
<td></td>
</tr>
<tr>
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<td>HIV</td>
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<td>HIV</td>
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</tr>
<tr>
<td>3</td>
<td>ISPA</td>
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<td>Other Primary Gonarthosis</td>
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<td></td>
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<tr>
<td>4</td>
<td>Ear diseases &amp; Prosesus Mastoid</td>
<td>4</td>
<td>Ear diseases &amp; Prosesus Mastoid</td>
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<td></td>
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<tr>
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<td>GED</td>
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</tr>
<tr>
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<td>GED</td>
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<td>Bronkitis, Emfisema &amp; Others Obstructive Pulmonary Diseases</td>
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<td>Faringitis</td>
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</tr>
<tr>
<td>10</td>
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</table>

10 Most Infectious Disease Cases at Outpatient Unit Year 2016 - 2018
# 10 Most Infectious Disease Cases at Inpatient Unit Year 2016 – 2018

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
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</thead>
<tbody>
<tr>
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<td>No</td>
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<tr>
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<td>Tuberculosis</td>
<td>3</td>
<td>Tuberculosis</td>
</tr>
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<td>GED</td>
<td>4</td>
<td>GED</td>
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<td>Sepsis</td>
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<td>Urinary Tract Infection</td>
</tr>
<tr>
<td>8</td>
<td>Typhoid Fever</td>
<td>8</td>
<td>Typhoid Fever</td>
</tr>
<tr>
<td>9</td>
<td>ISPA</td>
<td>9</td>
<td>DHF</td>
</tr>
<tr>
<td>10</td>
<td>Urinary Tract Infection</td>
<td>10</td>
<td>Sepsis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 Urinary Tract Infection</td>
</tr>
</tbody>
</table>

- 10 most infectious Disease cases at inpatient unit year 2016 – 2018

- Chronic Obstructive Pulmonary Disease
**Surveillance, Infection Prevention & Control**

- Health Promotion, Collaboration human-animal
- Animal early warning

1. **Preparedness**
- Surveillance, Infection Prevention & Control
- Health Promotion, Collaboration human-animal
- Animal early warning

2. **Alert**
- Epidemiological Investigation
- Specimen Collection/shipment
- Assess need and resources
- Interpret laboratory result
- Take a decision

3. **Control**
- Implement control strategies
- Coordination, Media Surveillance, laboratory
- Social intervention
- Case management, IPC
- Physiological support
- Ethical Issues
- Logistic
- Environment

4. **Evaluation**
- Evaluation outbreak management & Documentation

**Graph:**
- Number of non-human primate cases of Ebola
- Number of human cases of Ebola

**Legend:**
- Rapid response
- Control Opportunity
- Early detection in animal and human cases
- Animal Amplification
- Logistic Environment

**NB:** the area in yellow represents cases that can be prevented through control activities.
Primary Health Care sends EWRS SMS reports every week to the server.
EWARS form PHC by SMS gateway

Source: PHEIC Office
Surveillance system in HMIS SS-IDH
(WAG and application e-SURETRIPSS)

EWARS form PHC / PHO by WAG
SURVEILLANCE
EPIDEMIOLOGY of DCI
FLOWCHART at SS-IDH

Patient Entered → TPP → EMG. Unit

TPP → Lab. Assessment → Out Patient Instalation

Lab. Assessment → Dx → Untreatment

Dx → Life → Last Dx

Dx → Inpatient → DoA

Dx → Death

SURVEILLANCE REPORT MECHANISM
1. Internal SS - IDH
2. DG of HS, MoH
3. DG of CDC, MoH
4. Provincial Government
DATA UTILIZATION

- Planning for Supplies
- Planning for Quality Services
- Planning for R & D
### Measles Case Trends by Month at the Inpatient Installation
**Year 2015-2018**

<table>
<thead>
<tr>
<th></th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>Mei</th>
<th>Juni</th>
<th>Juli</th>
<th>Agust</th>
<th>Sept</th>
<th>Okt</th>
<th>Nov</th>
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<td>4</td>
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<td>3</td>
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<td>0</td>
<td>2</td>
<td>5</td>
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<td>4</td>
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<td>15</td>
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<td>20</td>
<td>12</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>2018</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>0</td>
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<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

### Number of Measles Cases by Age Group at the Inpatient Installation, Year 2015-2018

**Anak**

- 2015: 24
- 2016: 87
- 2017: 4
- 2018: 1

**Dewasa**

- 2015: 1
- 2016: 1
- 2017: 5
- 2018: 1

### Number of Measles Cases by Gender at the Inpatient Installation, Year 2015-2018

**Laki-Laki**

- 2015: 15
- 2016: 10
- 2017: 4
- 2018: 1

**Perempuan**

- 2015: 10
- 2016: 45
- 2017: 2
- 2018: 0
TETANUS SURVEILLANCE

Tetanus Case Trends by Year at the Inpatient Installation, Year 2015-2018

Number of Tetanus Cases by Age Group at the Inpatient Installation, Year 2015-2018

Number of Tetanus Cases by Gender at the Inpatient Installation, Year 2015-2018

Number of Tetanus Cases by Patients Domicile at the Inpatient Installation, Year 2015-2018
DIPHTHERIA SURVEILLANCE

Trends of Diphtheria Case in Inpatient Installation, Year 2015-2018

Number of Diphtheria Cases by Age Group in Inpatient Installation, Year 2015-2018

Number of Diphtheria Cases by Gender in Inpatient Installation, Year 2015-2018

Number of Diphtheria Cases by Patients Domicile in Inpatient Installation, Year 2015-2018

- Trends of Diphtheria Case in Inpatient Installation, Year 2015-2018
- Number of Diphtheria Cases by Age Group in Inpatient Installation, Year 2015-2018
- Number of Diphtheria Cases by Gender in Inpatient Installation, Year 2015-2018
- Number of Diphtheria Cases by Patients Domicile in Inpatient Installation, Year 2015-2018
Outcome of Diphtheria

January - October 2018

- Survive: 94.2%
- Decease: 5.8%
Surveillance of Inpatient Diphtheria Cases at RSPI Prof. Dr. Sulianti Saroso in 2015 - 2017

Herlina*, Farah Ghina Arifah, Bambang Setiaji
RSPI Prof. Dr. Sulianti Saroso, Kementerian Kesehatan Republik Indonesia

*Korespondensi Penulis:
Email: herlinadwinantomashud@gmail.com
HP. 0815-1965-2397

Abstract
Background: almost every part of the world in the form of an epidemic. This disease mainly attacks children aged 1-12 years, is easily transmitted and spread through direct contact. Efforts to prevent diphtheria are carried out through immunization programs. This epidemiological surveillance activity aims to draw an overview of the epidemiological surveillance of inpatients with a case of diphtheria in the year 2015 - 2017 based on the individual, place, and time. Method: this epidemiological surveillance activity employs the passive surveillance method, namely by collecting patient data from the medical records. Results: there was an increase in the number of inpatient diphtheria cases. The number of inpatients in 2015 was 16 patients, in 2016 it was 37 patients, and in 2017 260 patients. The culture tests showed that there were 2 cases with a positive culture test result in 2015, 5 in 2016, and 17 in 2017. Conclusion: There was an increase in the number of inpatient diphtheria cases in RSPI-SS, with the number of cases in 2017 increasing dramatically. Suggestion: It is necessary to develop preparedness to mitigate diphtheria cases, especially upon the discovery of a case so that disease control can be carried out to break the chain of diphtheria transmission.

Keywords: epidemiological surveillance, diphtheria
Overview of Characteristics and Administration of Anti-Diphtheria Serum (ADS) in Diphtheria Patients of the Infectious Diseases Hospital Prof. Dr. Sulianti Saroso in the Year of 2014-2016

Anita Puspitasari*, Dedet Hidayati, Maya Marinda Mountain, Kunti Wijiarti, Farida Murtiani
Rumah Sakit Penyakit Infeksi Prof. Dr. Sulianti Saroso

Korespondensi Penulis :
Anita Puspitasari
Email: nita.pdn@gmail.com

Abstract
Background: Diphtheria is an acute infectious disease caused by the bacterium Corynebacterium diphtheriae. Based on the surveillance data of the Epidemiology Division of RSPI Prof. Dr. Sulianti Saroso, from 2014 to 2016, there were 3 diphtheria cases in 2014, 16 cases in 2015 and 37 cases in 2016 (CFR 3.40%). In addition to the increasing need for ADS at the RSPI Prof. Dr. Sulianti Saroso, it happened that the hospital’s pharmacy also ran out of ADS stock. The purpose of this study to draw an overview of the characteristics and administration of ADS in diphtheria patients of RSPI Prof. Dr. Sulianti Saroso. Method: This is a descriptive quantitative research with the secondary data taken from the Medical and Pharmaceutical Records, totaling 56 files. Results: The majority of the diphtheria patients are 6-11 years old (41.5%), male (54.7%), from DKI Jakarta (50.9%), and referred by private hospitals (54.7%). There were 2 cases with a positive culture test result in 2015 and 4 cases in 2016. The total amount of ADS administered was 6 vials in 2014, 43 vials in 2015, while in 2016 the total needed was 99 vials but the amount available was only 92.5 vials. Conclusion: Learning from the inadequate ADS administration in 2016. Suggestion: it is recommended that ADS should always be available because it is the main medication for diphtheria patients.

Keywords: Diphtheria, ADS, inadequacy
Percentage of Measles Immunization in Indonesia
Year 2007-2016

Source: Indonesian Health Profile 2017
COVERAGE OF TT5 IMMUNIZATION ON ELIGIBLE WOMAN IN INDONESIA YEAR 2016

Source: Indonesian Health Profile 2017
DROP OUT NUMBERS of DPT / HB1-Measles IMMUNIZATION IN BABY YEAR 2007-2016

Source: Indonesian Health Profile 2017
Coverage of Basic Immunization In Baby By Province Year 2016

Source: Indonesian Health Profile 2017
Vaccination Issues in Indonesia

1. Anti-Immunization Movement:
   - Back to nature
   - Limited access
   - Religion

2. Incomplete immunization.

3. Pros and cons of “HALAL” vaccine.
LAWS OF THE REPUBLIC OF INDONESIA
NUMBER 33 YEAR 2014 REGARDING HALAL PRODUCT GUARANTEE
2019

- Government Regulation Number 31 Year 2019:
  - Regulation of Implementation of Law Number 33 / 2014 regarding Halal Product Guarantee;
  - As of October 17, 2019, Law 33 of 2014 concerning Halal Product Guarantee was officially enacted;
  - One of the mandates of this Act is the establishment of the Halal Product Guarantee Agency (BPJPH) as a halal certificate issuing body and all food and cosmetics products circulating in Indonesia for Muslims must be halal-certified.
HALAL ISSUE

Priority Covered:
food beverage products, cosmetics, medicines, and other products on stage

The Ulama Council of Indonesia (MUI)

http://www.halalmui.org/mui14/index.php/main/go_to_section/58/1366/page/1
HALAL ISSUE


**Data Sertifikasi Halal**

Jumlah Perusahaan

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Jumlah Produk

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http://www.halalmui.org/mui14/index.php/main/go_to_section/58/1366/page/1
CLINICAL RESEARCH / CLINICAL TRIAL
at SS IDH
Institutional Ethics Committee

Critical point of the assessment elements in the SNARS ed.1 accreditation standards
National Health Insurance Partnership Policy

National Health Insurance Agency (BPJ S)

Health Facilities with National Accreditation (KARS) → Hospital: SNARS Ed.1
Monitoring Clinic for Clinical Research / Clinical Trial
Method's Development for Early Detection of TB in HIV Patient

60% process

Research Network with 5 PHC

Volunteers Enrolled

CRU activities

Collab with MR Unit

Data Analysis activities

Collab with Clinic Mon Unit

AHS – UI MoU / IA

Operational Research

Basic data

Retrosp. Research

Prospective Research (OR)
Diagnostic Kit Development for Early Detection of Hep-B

- Clinical Trial non Intervention
- Basic data from ITB Univ.
- Lab Test
- Prospective Research (CR)
- Research Network with 5 PHC
- volunteers Enrolled
- 80% process
- CRU activities
- MoU IA
- Collab Data Analysis
- Collab with Clinic Mon Unit
- AHS – UI MoU / IA
the Flowchart of Clinical Trial Submission
Legal Basis for the Protection of Biological Materials

- **Law NO 18/ 2002** regarding the National System of Research and Development;
- **Law Number 36 Year 2009** regarding Health;
- **Government Regulation Number 39 Year 1995 article 6** regarding Health Research and Development.
- **Government Regulation 41/ 2006** regarding Licensing Conducts Research and Development Activities for Foreign Universities (PTA), Foreign Research and Development Institutions (LPPA), Foreign Business Entities (BUAs) and Foreigners (OA) and the Application of Science and Technology;
- **Minister of Health Regulation No. 657 / 2009** regarding the delivery and use of clinical specimens, biological material and information content (to overseas).
LAWS OF THE REPUBLIC INDONESIA
NUMBER 11 /2019 regarding NATIONAL SYSTEM OF KNOWLEDGE & TECHNOLOGY

FOREIGN RESEARCHERS IN THE LAW OF THE REPUBLIC OF INDONESIA A NUMBER 11 / 2019 regarding NATIONAL SYSTEM OF KNOWLEDGE & TECHNOLOGY
1. Network and Partnership: Article 72 of Law 11/2019
2. Licensing: Article 75 of Law 11/2019
5. Mandatory Submission and Obligatory to Save Primary Data: Article 40 of Law 11/2019
7. Supervision: Article 91 paragraph (2) of Law 11/2019
Criminal Sanctions: Article 93 of Law 11/2019

1. In the event that a foreigner as referred to in Article 92 again violates conducting Research, Development, Study, and Application of Science and Technology in Indonesia without permission, shall be liable to a maximum fine of Rp.4,000,000,000.00 (four billion rupiah).

2. In addition to the principal crime as referred to in paragraph (1), an additional criminal offense may be subjected to in the form of a prohibition to obtain a research permit in the territory of the Republic of Indonesia for a maximum period of 5 (five) years.
1. Research Contract
   a. Pharmaceutical Company – CRO - Site
   b. Benefit – Sharing

2. Central Lab at Overseas
   ➢ Central lab. In Indonesia ➔

3. IPR
**TYPE 3 - RESEARCH PURPOSE**

**MTA FORM**

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### EX.

| [name of institution], a research / | [name of institution], an Indonesian government / non-government institution existing under the laws of | [address] (hereinafter referred to as “First Party.”) |
| represented by | Republic of Indonesia, having its registered office at | |
| [name of institution], a research / | [name of institution], an Indonesian government / non-government institution existing under the laws of | [address] |
| [address] and | Indonesia | |
| [position] and | [capacity as] | |
| [name of Scientist], domiciled at | in this matter acting in his | |
| [country], having its | | |
| | | |

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**MATERIALS TRANSFER AGREEMENT**

This Materials Transfer Agreement is made on this day, [date, month, year] by and between [name of institution], a research / | [name of institution], an Indonesian government / non-government institution existing under the laws of | [address] |
| represented by | Republic of Indonesia, having its registered office at | |
| [name of institution], a research / | [name of institution], an Indonesian government / non-government institution existing under the laws of | [address] |
| [address] and | Indonesia | |
| [position] and | [capacity as] | |
| [name of Scientist], domiciled at | in this matter acting in his | |
| [country], having its | | |
| | | |

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**LAMPIRAN I**

KEPUTUSAN MENTERI KESEHATAN

KEPINDAHI, 14 AGUSTUS 2009

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**www.mta.litbang.depkes.go.id**
STRATEGIC PLANNING HEALTH DEVELOPMENT FOR 2020-2024
(HEAD OF PLANNING AND BUDGET BUREAU GENERAL SECRETARIAT, MINISTRY OF HEALTH)

PENYUSUNAN RENCANA STRATEGIS PEMBANGUNAN KESEHATAN TAHUN 2020-2024

Oleh:
KEPALA BIRO PERENCANAAN DAN ANGGARAN
SEKRETARIAT JENDERAL KEMENTERIAN KESEHATAN
KERANGKA PEMBANGUNAN RANCANGAN TEKNOKRATIS RPJMN 2020-2024

VISI 2045
Berdaulat, Maju, Adil Dan Makmur

2020-2024
Mewujudkan masyarakat Indonesia yang mandiri, maju, adil, dan makmur melalui percepatan pembangunan di berbagai bidang dengan menekan terbangingnya struktur perekonomian yang koh berlandaskan keunggulan kompetitif di berbagai wilayah yang didukung oleh SDM berkualitas dan berdaya saing.

TEMA
Indonesia Berpenghasilan Menengah-Tinggi yang Sejahtera, Adil, dan Berkesinambungan

PEMBANGUNAN MANUSIA
1. Pelayanan Dasar dan Perlindungan Sosial
2. SDM Berkualitas dan Berdaya Saing
3. Pembangunan Karakter

PEMBANGUNAN EKONOMI
1. Pangan
2. Energi
3. Pariwisata, Ekonomi Kreatif dan Digital
4. Industri Manufaktur
5. Kelautan dan Kemasitaman

PEMBANGUNAN KEWILAYAHAN
1. Sentra-Sentra Pertumbuhan
2. Komoditas Unggulan Daerah
3. Pertumbuhan Perkotaan

PEMBANGUNAN INFRASTRUKTUR
1. Transportasi
2. Telekomunikasi
3. Sumber Daya Air
4. Perumahan dan Pemukiman

PEMBANGUNAN POLITIK, HUKUM, PERTAHANAN & KEAMANAN
1. Hukum dan Regulasi
2. Portahan dan Keamanan
3. Politik

Development Constraints :
Kondisi Investasi
Kondisi SDA

PENGARUSUTAMAN

Kesetaraan Gender
Tata Kelola (Governance)
Kerentanan Bencana
Perubahan Iklim
Modal Sosial Budaya

Kaidah Pembangunan :
Membangun Kemandirian
Menjamin Keadilan
Menjaga Keberlanjutan
## Kandidat Indikator Pembangunan Kesehatan - RPJMN 2020 - 2024 (1)

### Meningkatnya Status Kesehatan Ibu dan Anak

<table>
<thead>
<tr>
<th>Indikator</th>
<th>Baseline</th>
<th>2024</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Angka kematian ibu (per 100,000 KH)</td>
<td>305</td>
<td>183</td>
</tr>
<tr>
<td></td>
<td>(SUPAS, 2015)</td>
<td></td>
</tr>
<tr>
<td>2. Angka kematian bayi (per 1,000 KH)</td>
<td>24</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>(SDKI, 2017)</td>
<td></td>
</tr>
</tbody>
</table>

### Meningkatnya Status Gizi Masyarakat

<table>
<thead>
<tr>
<th>Indikator</th>
<th>Baseline</th>
<th>2024</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Prevalensi stunting balita (%)</td>
<td>30,8</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>(Risikesdas, 2018)</td>
<td></td>
</tr>
<tr>
<td>2. Prevalensi wasting balita (%)</td>
<td>10,2</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>(Risikesdas, 2018)</td>
<td></td>
</tr>
</tbody>
</table>

### Meningkatnya Pengendalian Penyakit Menular dan Faktor Risiko Penyakit Tidak Menular

<table>
<thead>
<tr>
<th>Indikator</th>
<th>Baseline</th>
<th>2024</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Insidensi TB (per 100,000 penduduk)</td>
<td>3,9</td>
<td>190</td>
</tr>
<tr>
<td></td>
<td>(Global TB Report, 2017)</td>
<td></td>
</tr>
<tr>
<td>2. Insidensi HIV (%)</td>
<td>0,24</td>
<td>0,18</td>
</tr>
<tr>
<td></td>
<td>(Pemodelan Kemkes, 2018)</td>
<td></td>
</tr>
<tr>
<td>3. Eliminasi malaria (Kab/Kota)</td>
<td>266</td>
<td>405</td>
</tr>
<tr>
<td></td>
<td>(Kemkes, 2017)</td>
<td></td>
</tr>
<tr>
<td>4. Merokok usia ≤ 18 tahun (%)</td>
<td>9,1</td>
<td>8,7</td>
</tr>
<tr>
<td></td>
<td>(Risikesdas, 2018)</td>
<td></td>
</tr>
<tr>
<td>5. Obesitas usia 18+ tahun (%)</td>
<td>21,8</td>
<td>21,8</td>
</tr>
<tr>
<td></td>
<td>(Risikesdas, 2018)</td>
<td></td>
</tr>
</tbody>
</table>
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