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Nationwide Mortality Studies To Quantify Causes Of Death: Relevant Lessons From India's Million Death Study

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ABSTRACT Progress toward the United Nations 2030 Sustainable Development Goals requires improved information on mortality and causes of death. However, causes of many of the fifty million annual deaths in low- and middle-income countries remain unknown, as most of the deaths occur at home without medical attention. In 2001 India began the Million Death Study in 1.3 million nationally representative households. Nonmedical staff conduct verbal autopsies, which are structured interviews including a half-page narrative in local language of the family's story of the symptoms and events leading to death. Two physicians independently assess each death to arrive at an underlying cause of death. The study has thus far yielded information that substantially altered previous estimates of cause-specific mortality and risk factors in India. Similar robust studies are feasible at low cost in other low- and middle-income countries, particularly if they adopt electronic data management and ensure high quality of fieldwork and physician coding. Nationwide mortality studies enable the quantification of avoidable premature mortality and key risk factors for disease, and provide a practicable method to monitor progress toward the Sustainable **Development Goals.**

he 2030 United Nations Sustainable Development Goals have become an organizing framework for assessing progress in global health and development.^{1,2} Seven of the targets under the third goal ("ensure healthy lives and promote well-being for all at all ages")¹ necessitate the measurement of causespecific mortality (Exhibit 1). Despite claims that progress toward the goals can be monitored using econometric modeling,³ models cannot distinguish between changes in specific causes of death and changes in modeling assumptions.^{4,5} Thus, direct nationwide epidemiological studies are needed to understand variation in progress toward the goals in subpopulations, such as in-

digenous or tribal populations and by sex or urban versus rural residency.

Health progress in India is particularly relevant to achieving global goals, as India has disproportionately large percentages of the world's poor and global premature mortality.² Indian mortality and cause-of-death statistics captured through the Million Death Study, initiated in 2002, provide a widely practicable and costeffective method to monitor progress toward meeting the Sustainable Development Goals.

In this article we describe the rationale for the Million Death Study and the relevance of similar low-cost nationwide mortality studies in other low- and middle-income countries.

We begin with a brief review of the current gaps

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EXHIBIT 1

Goal number and title Target 3. Ensure healthy lives and promote well-being for all at all ages 3.1 By 2030, reduce the global maternal mortality ratio to less than 100,000 live births 3.2 By 2030, end preventable deaths of newborns and children under age, with all countries aiming to reduce neonatal mortality to at least	
well-being for all at all ages 100,000 live births 3.2 By 2030, end preventable deaths of newborns and children under	
 12 per 1,000 live births and under-5 mortality to at least as low 1,000 live births 3.3 By 2030, end the epidemics of AIDS, tuberculosis, malaria, and recommunicable diseases 3.4 By 2030, reduce by one third premature mortality from noncom diseases through prevention and treatment and promote mental hell well-being 3.5 Strengthen the prevention and treatment of substance abuse, in narcotic drug abuse and harmful use of alcohol 3.6 By 2020,^a halve the number of global deaths and injuries from reaccidents 3.9 By 2030, substantially reduce the number of deaths and illnesse hazardous chemicals and air, water, and soil pollution and contamination. 	5 years of as low as as 25 per neglected other nunicable ealth and cluding ad traffic s from
11. Make cities and human settlements inclusive, safe, resilient, and sustainable inclusive inclusive, safe, safe,	sses luding
 16. Promote peaceful and inclusive societies for sustainable development, provide access to justice for all, and build effective, accountable, and inclusive institutions at all levels 16.1 Significantly reduce all forms of violence and related death rate everywhere 	25

SOURCE United Nations Economic and Social Council. Report of the Inter-Agency and Expert Group on Sustainable Development Goal indicators (Note 1 in text). **NOTE** In addition, many Sustainable Development Goals require information on the underlying population (or subpopulation) as denominators. ^a2020 is an error in the report. It should be 2030, but official UN reports have retained this error.

in global cause-of-death data. We provide details of the methods used in the Million Death Study, emphasizing the importance of robust systems that capture deaths where they primarily occur at home, not in hospitals. We then describe the impact of the study on public health in India, and we discuss some of the study's key innovations.

The Context

Most of the fifty million deaths in low- and middle-income countries (out of the sixty million deaths worldwide) each year occur at home, without medical attention.^{4,6} Hence, the causes of death remain mostly unknown, particularly in sub-Saharan Africa and Asia. For example, only 3 percent of the world's children who died in 2010 had a death certificate.⁷ This lack of information limits the rapid identification of new diseases and outbreaks of existing diseases (such as Ebola); hampers population-based research on risk factors; and reduces accountability for health expenditures and programming, including those relevant to the Sustainable Development Goals.

Complete registration of deaths involves capturing both the act of death and the cause of death. Gaps in data on the causes of death represent the most important gap in global evidence. Many low- and middle-income countries have registration systems that cover only part of their populations, with little or no cause-of-death data for people who die outside of hospitals and limited routine compilation of data for the purposes of analysis, dissemination, and policy.⁶ As noted above, hospital deaths remain a minority of all deaths in these countries, whereas during the past hundred years or so most deaths in highincome countries have shifted from homes to hospitals or similar facilities.8 Furthermore, most households in low- and middle-income countries have few incentives to report deaths (in contrast to increasing incentives to register births, such as requiring birth certificates to enroll children in school). The share of deaths registered in low- and middle-income countries was

The Million Death Study has shown that capturing and quantifying cause-ofdeath data can be done at low cost, with high quality, and in a timely manner.

mostly unchanged, averaging about 37 percent from 2000 to 2012, while the share of births registered rose modestly, from 58 percent to 65 percent.^{6,9} Thus, alternative systems are needed to determine causes of death at the population level in these countries.

Before 2002, causes of the approximately ten million annual deaths in India were unknown, as most deaths occurred outside of hospitals and in rural areas. Hence, the Registrar General of India, working closely with academic partners, launched the Million Death Study to understand nationally representative patterns of deaths.¹⁰

Study Data and Methods

Detailed explanations of the methods of the Million Death Study have been published elsewhere.^{11,12} In brief, the study uses verbal autopsies to survey living family members or other close associates of the dead. These autopsies are structured interviews conducted by nonmedical fieldworkers and include questions about medical history and key symptoms as well as a half-page local language narrative of the family's story of the symptoms and events leading to death.¹³ Verbal autopsies have been used for decades to determine childhood causes of deaths that occur outside of health care facilities.¹⁴ The study has extended their use to deaths at all ages in India using careful quality-control efforts and dual physician coding.^{10,12} (For a flowchart of field data collection through to the assignment of causes of death, see online Appendix 1.)¹³

STUDY SETTING The Million Death Study is conducted within the Registrar General of India's nationally representative Sample Registration System. In this system, several thousand small areas throughout India—either villages or urban census enumeration blocks, each typically containing 1,100–1,400 people—are chosen randomly every ten years from the preceding census.10 Events in the homes in these areas are monitored on a half-yearly basis for the next decade. The system monitored 6,671, 7,597, and 8,775 small areas drawn from the 1991, 2001, and 2011 censuses, respectively. The current sampling frame (covering the period 2014-23) covers about eight million people in about 1.4 million homes. In each of the small areas, a resident part-time enumerator (typically a local teacher) ascertains every month the numbers of births and deaths that have occurred in each household, but not the causes of death. One of about 900 Registrar General of India surveyors visits the homes in these areas every six months to independently record details of all births and deaths and conducts a verbal autopsy on each death using a simple two-page questionnaire administered in the local language.¹⁴

PHYSICIAN CODING Two of about four hundred physicians review online each completed verbal autopsy and independently assign a diagnosis for the underlying cause of death using the World Health Organization's (WHO) *International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision (ICD-10). Disagreements (which occur about 30 percent of the time) undergo anonymous reconciliation, with a more senior physician adjudicating any persisting differences (which occur about 10 percent of the time).¹⁵

LIMITATIONS Two limitations are important to note. First, while the Million Death Study is a large study, it lacks statistical power for less common causes of death—most notably, maternal death. However, for most other conditions of major public health interest, deaths before age seventy occur in sufficient numbers to generate plausible mortality rates and relative risks for death for selected risk factors.

Second, using verbal autopsies to determine causes of death is by necessity crude, but is reasonably robust for deaths before age seventy. Despite the inherent misclassification of verbal autopsies, they are an order of magnitude better than the lack of any nationally representative data and superior to model-derived estimates.^{11,12}

Study Results

Of the deaths in India in the period 2001–13 that had been assigned a cause of death before July 2016, about two-thirds occurred before age seventy, one-sixth before age five, and onetenth in the first month of life (Exhibit 2).

HOSPITAL VERSUS HOME-BASED DEATHS A key lesson from the Million Death Study is to avoid

EXHIBIT 2

Numbers of study deaths in India, by age and sex, 2001-13

	Male deaths		Female deaths		All deaths	
Age	Number	Percent	Number	Percent	Number	Percent
0–28 days	29,044	8.9	23,208	9.1	52,252	9.0
1-59 months	20,216	6.2	21,841	8.6	42,057	7.2
5–14 years	7,723	2.4	7,478	2.9	15,201	2.6
15-29 years	21,943	6.7	18,121	7.1	40,064	6.9
30–69 years	150,560	46.1	92,428	36.3	242,988	41.8
70 or more years	97,266	29.8	91,632	36.0	188,898	32.5
All ages	326,752	100.0	254,708	100.0	581,460	100.0

SOURCES Authors' analysis of data from the Registrar General of India and the Centre for Global Health Research. **NOTES** The percentages are of the 0.6 million deaths in the period 2001–13 that were assigned a cause of death in the Million Death Study before July 2016. Percentages may not sum to 100 because of rounding.

using hospital-based deaths as a "gold standard" for the distribution of causes of death for deaths occurring in the community. Hospital-based deaths are a poor choice to "validate" verbal autopsies among unattended rural home deaths since variables such as the age and education of the deceased person, pathogen distribution, and causes of death differ greatly between rural unattended deaths and hospital-based deaths. The Million Death Study showed sharp differences in the proportion of deaths from various causes between hospital and home deaths, even after adjustment for differences in education, age, and rural/urban residence^{12,16} (Exhibit 3). Thus, "validation studies" that use hospital records to determine distributions of causes of

EXHIBIT 3

Percentages of deaths of people ages 5-69 years from selected causes, in India, by source of data and place of death, 2001-03

	Source of data (r of deaths)	numbers	Place of death (numbers of deathsª)	
Cause of death	RGI surveyors (63,139)	Resample teams (1,811)	Home (43,979)	Hospital (10,779)
Heart attack	12.0	13.2	11.3	14.8****
Other infectious disease	11.1	12.9***	14.6	10.7***
Tuberculosis	9.0	7.7	10.8	5.9***
Cancer	8.7	8.4	9.5	9.1***
Chronic lung disease	8.7	7.4	10.6	4.8****
Stroke	7.2	7.6	7.5	8.4***
Suicide	4.2	3.3	3.3	4.7
Renal and other endocrine diseases	4.0	3.7	1.9	2.6***
Liver cirrhosis	3.9	3.3	3.9	5.1
Malaria	3.3	2.2	3.7	3.0
Road traffic accidents	3.0	3.9	0.5	4.5***
Maternal conditions ^b	1.7	0.8***	1.2	3.2***
HIV or other sexually transmitted infection	0.7	0.4	0.8	0.5***
Ill-defined cause	6.0	6.0	5.9	3.4***
All other causes	16.6	19.2***	14.5	19.4****

SOURCE Authors' analysis of data for deaths in 2001–03 from the Million Death Study. **NOTES** There were nine hundred Registrar General of India (RGI) surveyors and seventy resample staff. The percentages were adjusted for age, rural or urban residence, and level of education. Percentages may not sum to 100 because of rounding. Significance refers to the differences between RGI surveyors and resample teams, or between home and hospital deaths. ^aExcluding 6,548 deaths occurring in other places and 1,833 deaths in unknown places. ^bMaternal conditions refers to "O" codes in *International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision. ^{****}p < 0.01

death in the community can be misleading.⁴

IMPACT ON PUBLIC HEALTH The Million Death Study has for the first time provided national, reasonably reliable age-specific and cause-specific death rates up to age seventy for India. The study's results have substantially altered previous estimates of mortality and risk factors. For example, it demonstrated that India has about one million deaths attributable to smoking each year, which is about three times higher than what the WHO had estimated earlier¹⁷ and about the same absolute death total as seen in China.¹⁸ The effect of smoking, particularly of cigarettes, on the risk of death was as large as observed in highincome countries, despite Indian men having lower smoking prevalence, having a later age of onset, and smoking fewer cigarettes or bidis per smoker.17 The Million Death Study also demonstrated that India had only about 100,000 premature HIV deaths in 2005, about a quarter of the total estimated by WHO models,¹⁹ but far more malaria deaths than the WHO had estimated.²⁰ Numbers of deaths from malaria in middle age remain uncertain, but in the more trustworthy findings for childhood deaths, the study found five times as many malaria deaths as the WHO had estimated. In retrospect, the WHO estimates were wrong because they were based on case-fatality rates in treated malaria patients, whereas most malaria deaths are in untreated people. The findings for childhood malaria deaths are generally accepted, and the much less certain findings for adult deaths have initiated an appropriate global discussion about how to obtain better estimates of the extent to which untreated malaria contributes to adult mortality.21

The Million Death Study's results have also drawn attention to other neglected areas of public health that were previously underestimated in terms of their impact on mortality. The study developed conditional sex ratio methods to estimate that as many as twelve million girls were aborted before birth in India over the past three decades-half of them just in the past decade. This documentation of the expanding use of selective abortion has helped trigger public debates and strengthened the implementation of laws to reduce this practice.^{22,23} The study also showed far more suicides among young adults than the Government of India had estimated. In addition, most of the suicides were among young adults rather than older farmers, who had been thought to have the highest numbers of suicide. Suicide rates in young adults were particularly high in south India, and many suicides were committed by ingesting organophosphate pesticide.24 The Million Death Study found about 60,000 pedestrian traffic deaths in 2005, whereas local police records reported only 9,000.²⁵ Finally, the study documented 50,000 snakebite deaths in 2005, which was the number of such deaths that the WHO had estimated occurred globally.²⁷ The WHO has subsequently revised its global snakebite death totals to 100,000 for 2015 and added snakebites to its list of priority neglected tropical diseases.²⁷

More generally, the Million Death Study has shown that each disease that is common in one part of India is relatively uncommon elsewhere, for reasons that are not yet fully understood. This means that there are important avoidable causes of death that still await epidemiological discovery. For example, while child mortality showed expected north-south gradients, adult mortality showed unexpected east-west gradients.^{28,29} The Million Death Study also documented the avoidability of particular conditions. For instance, it found that the leading cause of cancer deaths in women was cervical cancer, a potentially avoidable cancer, with about 33,000 cervical cancer deaths among women ages 30-69 in 2010. However, if the rates seen in the states of Kashmir and Assam, where a large proportion of the population is Muslim, were applied nationally, only 7,000 women would have died that year.³⁰

A recent analysis of data from the Million Death Study has shown that India avoided about one million additional child deaths in the period 2005-15 with the country's accelerated progress in reducing child mortality since 2005,³¹ but it could easily have avoided three million child deaths if progress nationally had matched that achieved by some states in the south. The Million Death Study identified the condition-specific rates of progress needed to achieve the Sustainable Development Goals. Attention to full-term births of infants with low birthweight is required. Continuing to reduce the mortality rates for children ages 1–59 months from pneumonia, diarrhea, measles, and especially malaria is also a priority (Exhibit 4).³¹

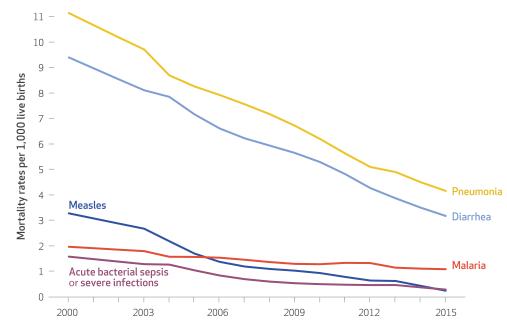
QUALITY OF THE MILLION DEATH STUDY A key measure of the quality of systems that report causes of death is a reduction in the proportion of deaths from unknown causes before old age.^{4,12} Compared to the earlier crude estimates of causes of death in the Sample Registration System as reported by households, the Million Death Study reduced the share of "ill-defined" death codes from 13 percent to 4 percent for people ages 5-69 and achieved a similar reduction for children younger than age 5. In comparison, the Indian District-Level Household Survey-4—which relied not on verbal autopsies but on causes reported by households-found that nearly half of child deaths did not have a classifiable cause.³² The Million Death Study re-

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EXHIBIT 4





SOURCE Authors' analysis of data from the Million Death Study.

duced the share of ill-defined deaths for people older than age 70 from 62 percent to a still sizable 18 percent. Hence, much like the medical certification of deaths in the United States, verbal autopsy is more reliable in childhood and middle age than it is in old age.⁴

Another evaluation of the study's quality was based on random resampling of the data on deaths collected by Registrar General of India surveyors. This was done on a 3 percent random sample of homes in 2004–05. Family members of 1,811 people who died at ages 5–69 were revisited and reinterviewed by independent teams, so as to compare the information from the resample and the original study sample. The proportions of deaths from major conditions and the rank order for the major causes of death were similar (Exhibit 3). Results were similar for deaths at ages younger than age 5 (data not shown).^{12,16}

Discussion

The major global gap in knowledge of causes of death, particularly for adults in low- and middleincome countries, could be filled by adopting nationally representative verbal autopsy surveys such as the Million Death Study. Ongoing investments in innovations for cause-of-death data reporting systems are required, as nationwide mortality studies, like health interventions, improve over time if they become cheaper, faster, better, and simpler.³³ In this section, we discuss a few of the innovations under way in the Million Death Study that are relevant to other low- and middle-income countries.

MEASURING RISK FACTORS There is a need to document not only the underlying cause of death, as defined by the WHO's ICD-10 codes, but also the key risk factors for death. Typically, infections (such as malaria) are directly related to the underlying cause of death (for example, cerebral malaria). However, even in the case of infections such as HIV and tuberculosis, there may well be genetic or environmental causes other than the relevant pathogen that make infections (or the progression of infections to diseases) more probable.³⁴ Much more remains to be discovered about the personal correlates of respiratory, intestinal, or other infections in general and about the avoidable causes (including tobacco use, adiposity, and environmental factors) of chronic diseases such as cancer, heart attack, stroke, and lung disease, which currently account for most of the adult mortality in India and other low- and middle-income countries.²

The Million Death Study has adopted several ways to document risk factors that contribute to death. This includes questions about key exposures of the deceased and of living respondents. For example, "household case control methods"—in which living men whose wives have died serve as controls for dead men, and

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living women whose husbands have died serve as controls for dead women—have been used to quantify the hazards of smoking.¹⁷ "Proportional mortality" methods are used to determine the number of excess deaths from a specific cause among exposed populations. For example, the prevalence of diabetes is compared in deaths caused by renal conditions to injury deaths, with the latter serving as controls.³⁵ Similar approaches have examined the prevalence of breast-feeding and immunization among children who died of pneumonia or diarrhea, compared to children killed in accidents.

ELECTRONIC DATA COLLECTION AND GPS TRACKING A major constraint of nationwide mortality studies is the ability to handle data. These studies require customized information technology solutions to collect, validate, manage, analyze, and report data, while ensuring the data's security and confidentiality. The Million Death Study initially collected, scanned, and entered data from paper-based forms. The use of paper proved to be a major reason for the initial delay in data processing. Beginning in 2018, the study will adopt electronic verbal autopsy.

We piloted an electronic verbal autopsy prototype in 2016 outside the Million Death Study, collecting information on 12,000 deaths in a total of five districts spread across three states of India. This involved the use of a ten-inch Connoi laptop running an offline application with an embedded database, thus eliminating the need for an Internet connection. The electronic verbal autopsy applies programming logic to ask first the symptoms most relevant to the probable cause of death specified by the respondent (that is, symptoms that are most likely to elicit positive replies) so as to hold the respondent's attention. The symptoms that are more likely to elicit negative replies are asked at the end of the interview. Furthermore, the electronic system makes it possible to ensure data quality in real time by validating the data as they are entered. Death records from the pilot data collection were available within two days of field work for physicians to code. Hence, implementation of the electronic verbal autopsy shortened the time between data collection and analysis from months to several weeks. The electronic verbal autopsy's built-in GPS tracking capability enabled the geocoding of house addresses, thereby providing a check against fraud in field work.

GEOSPATIAL LINKAGES With the widespread use of GPS devices and geospatial mapping, it is now possible to map the occurrence of diseases. Geospatial mapping is useful in investigating health disparities and in identifying at-risk populations.³⁶ This technique also allows links to be established between locations of cause-specific mortality and environmental exposure, thereby measuring the impact of location on health. The maps allow complex relationships to be rendered and interpreted with relative ease and assist in geographically targeting health interventions. Geospatial methods that link access to health care to health exposures or outcomes (such as access to functional surgical facilities) have been used to quantify surgically averted mortality in India.³⁷ Similarly, analyses of geospatial linkages of air pollution exposures with cause-specific mortality are under way.

KNOWLEDGE TRANSLATION Scientific reporting of the epidemiological patterns of disease and risk factors needs to be complemented with active knowledge translation efforts to use these death statistics to improve public health programs and set priorities. The Million Death Study has two strategies for knowledge translation. First, the Registrar General of India, a government agency that is housed in the Ministry of Home Affairs, is responsible for collecting key demographic and mortality data for the country. It does so independently of the Ministry of Health. This de facto separation of users and producers of data adds to the credibility of results. It also avoids the commonly noted underor overreporting of coverage indicators that are often seen in utilization data gathered by ministries of health.⁴

Second, in partnership with the Indian Council of Medical Research, the Million Death Study has formed working groups on major disease priorities to examine the major mortality trends from 2000 to 2015 and provide corrective actions for major disease control programs relevant to the 2030 Sustainable Development Goals.³¹

COSTS There is little information on the cost of nationwide epidemiological studies in low- and middle-income countries. In part, this is due to the difficulty of pricing the value of information.³⁸ The running costs of the Million Death Study are currently less than US \$1 million per year, which includes all field costs and physician coding costs (the per death cost of field work and physician coding is about US \$1). Overall monthly costs for each district with a population of two million are approximately US \$30,000. The marginal costs arise mostly from field staff time (about 60 percent), followed by physician coding (about 21 percent). Costs of data collection mainly include the salaries of surveyors and transportation costs. Training and refresher training also have costs. The costs for information systems and hardware, plus managerial costs, account for a smaller share (6 percent), and overhead costs are estimated to account for 13 percent.

Policy Implications

The Million Death Study reinforces the importance of direct measurement of causes of death.⁴ Indirect model-based methods, including the Global Burden of Disease study and the WHO's Global Health Estimates,^{3,9} complement but do not substitute for annual nationally representative data on causes of death. Moreover, modelbased estimates cannot distinguish between trends due to changes in model assumptions and those due to actual changes in mortality rates. Many countries in Africa and Asia still have inadequate vital registration systems and do not use medical reports to document causes of death.⁶

Experience with the Million Death Study demonstrates the importance of integrating cause-ofdeath data into national civil registration and vital statistics systems.³⁹ This integration includes strengthening census operations and capture of home and facility births and deaths. The proportion of facility-based deaths is slowly growing in low- and middle-income countries. The basis of facility-based reporting is the WHO standard death certificate that requires physicians to assign immediate, intermediate, and (most important) underlying causes of death. The quality of reporting on causes of death in health-facility registries is generally poor in lowand middle-income countries. To remedy this, the Million Death Study has created the Advanced Course on Death Certification, which provides online training and certification on the completion of the WHO death certificate.⁴⁰

Conclusion

Counting the dead and describing the causes of their deaths are central to reducing premature mortality worldwide. Throughout the next few decades, most deaths in low- and middle-income countries, including India, will continue to occur at home. The Million Death Study has shown that capturing and quantifying cause-of-death data can be done at low cost, with high quality, and in a timely manner. Electronic data systems can enhance the rapid capture, assignment, and reporting of these data. The generation and use of good-quality information on causes of death, linked to national programs, provide a practicable method to monitor progress toward the Sustainable Development Goals.

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