Original article:
Prevention of Chronic Non-Communicable Diseases in Russia: Analytical Review of General Institutional Issues
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Abstract
Objective: The purpose of this research is to assess regulatory, organizational and methodological documents, as well as Russian and international recommendations, to use information from them to identify and systematize problems in prevention of chronic non-communicable diseases, and to offer solutions. Materials and Methods: Analysis encompasses the key Federal Laws of the Russian Federation; orders, records, and reports provided by various ministries and departments of the Russian Federation, as well as by the leading research institutes; guides, manuals, and federal recommendations; the latest Russian and foreign guidelines and recommendations on prevention of chronic non-communicable diseases. Results and Discussion: Analysis was faced with a number of problems: poor correlation between changes in regulatory documents governing the prevention of chronic non-communicable diseases; incomplete allowance for international experience and guidelines on prevention of chronic non-communicable diseases, incomplete epidemiological data; poor coordination and uneven assignment of responsibilities in structures involved in prevention; shift in emphasis from population-oriented prevention and high-risk groups towards secondary prevention; below-satisfactory efficiency of tuberculosis screening in clinical examination. Conclusions: Their resolution may significantly increase the effectiveness of measures intended for prevention of chronic non-communicable diseases and their risk factors from occurrence in Russia.

Keywords: chronic non-communicable diseases; regulatory documents; prevention strategy; evidence-based medicine

Introduction
Chronic non-communicable diseases (NCDs) account for about 75% of death cases among adults in Russia, causing demographic losses and GDP losses, down 3% annually¹. This defined the priority of Russian demographic policy until 2025 – socially significant reduction of CNCD and their risk factors (RF), as well as motivation of population to a healthy lifestyle (HLS)².

Public health policies in most countries are driven by outbreaks of non-communicable diseases (NCDs), which become the leading cause of death and disability. According to experience of countries where death rates from these diseases display a steady decline, institutional preventive measures are effective when it comes to control over NCDs if introduced on an interdepartmental basis. Such measures imply not only improving of the health care system, but also improving of a responsible attitude to health among the population, as well as providing of conditions for a healthy lifestyle. This tentacles almost all spheres of society (governmental, political, public, cultural, religious, and business spheres).

In Russia, prevention of NCDs has been priority in the field of public health since 1993, but the first WHO Global Ministerial Conference held in Moscow on April 2011 with the participation of more than 800 delegates from 164 member countries was

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a crucial event that strengthened state and public efforts in this direction. At this conference, problems of a healthy lifestyle and control over NCDs were not only essential – the emphasis was placed on a sector wide approach to solving them. Emphasized was the significance of making preventive services a must routine to take in the health care system, especially in primary health care (PHC), thereby creating a unified preventive platform.

The greatest boost to NCD prevention improvement was given in primary health care of the Russian Federation in 2013, when a new methodological and organizational basis was introduced to general screening practice for adults. Mass screening examination of adult population was chosen as a measure that could accelerate the decline in death rates, which is still insufficient. Medical screening examination refers to high-risk strategic measures intended for reduction of premature mortality. This strategy centers around identification of individuals that are at increased risk of NCD development. In Russian-language literature, general medical examination is the term to describe a preventive strategy that implies check-ups and statistical analysis, while abroad, this term is screening. According to the UK National Screening Committee, screening is a systematic application of a test or inquiry, to identify individual at sufficient risk of a specific disorder to warrant further investigation or direct preventive action, amongst persons who have not sought medical attention on account of symptoms of that disorder.

The world accumulated great experience in conducting mass surveys, namely in screening. In most national programs of Europe (Lithuania, Belgium, Denmark, the United Kingdom, Ireland, Spain, Italy, the Netherlands, Finland, France, Sweden, Hungary, Latvia, Slovakia, Estonia, etc.), NCD risk identification is currently focused on those risk factors affecting NCD emergence and development that arise from lifestyle and behavioral habits (tobacco smoking, low physical activity, unbalanced nutrition, excessive alcohol consumption, etc.).

In Russia, medical screening examination has a long history. Preventive framework of national health care was established from the moment of system creation. Prevention is the path we take, screening is a method for solving preventive problems (from speeches of N.A. Semashko, the first the first Soviet People’s Commissar of Public Health). Although public health protection priorities were different those days, preventive focus of health care was clear. The first detailed and most complete national program of medical examination was adopted in 1986. However, its implementation was accompanied with organizational difficulties, which were not taken into account at development stages they should be, as well as with a number of methodological drawbacks associated with the content of a survey program, and with evaluation criteria. This is why in 1986, medical screening examination was a costly and organizationally complex practice that proved to be performance-inhibitive to polyclinics, and not effective enough as well. As a result, doctors and the population have formed a rather formal likely negative attitude towards its implementation that has been standing there for many years.

On a regular basis, medical screening examination was re-implied in 2006. This time practice was guided by the principle of occupational preventive medical check-up. This event was much smaller with an annual involvement of about 2.5 to 4 million people of working age (about 75 million working citizens in total). Still, this organizational model of medical examination had methodological and organizational shortcomings of its own. Medical screening examination was organized by specialization, which in practice broke the continuity between doctors conducting these medical and primary care physicians, general practitioners or family physicians. The consequence here was a disturbance of additional examination process conducted for clarification, and of necessary medical interventions, including preventive ones.

Active implementation and updating of medical examinations and screening were catalyzed by the Federal Law No. 323-FZ on Basics of Health Protection of the Citizens in the Russian Federation, dated 21.11.2011. Guided by its implementation plan, the Ministry of Health adopted the Procedure of Health Examination of Certain Population Groups on December 3, 2012 (hereinafter referred to as the Screening Procedure), which was developed with regard to peculiarities of population health care organization in Russia, previous experience in medical examinations, and international experience in population screening. The Procedure for Preventive Health Examination was adopted in parallel with the Screening Procedure. Preventive medical examination, considered as a shorter version of screening, serves as a substitute tool in years when a citizen is not subject to screening examination. Besides those two procedures, a regular check-ups
procedure was adopted on December 21, 2012, No. 1344n⁴, which defines the process of controlling NCDs and other chronic diseases after detection. Even though a range of strategic measures was undertaken, this analysis shows that the existing concept of prevention of chronic NCDs involves poorly developed mechanisms of solving that problem. At this point, regulatory documents should be revised for conformity with one another and with Russian and international clinical guidelines. The untimely emergence of organizational and methodological support becomes an obstacle to a unified coordination of preventive measures in practice. So far, their effectiveness is reduced. The purpose of this research is to assess regulatory, organizational and methodological documents, as well as Russian and international recommendations, to use information from them to identify and systematize problems in prevention of chronic non-communicable diseases, and to offer solutions.

**Material and methods**

In modern Russia, pressing nature of chronic NCD issues together with public concern triggered the adoption of the Order of the Ministry of Health No. 455 on Improving of Disease Prevention in Public Health Bodies and Institutions of the Russian Federation in 2003, which outcompleted previous Orders, No. 364 of December 22, 1995, and No. 295 of October 6, 1997. This Order is still in effect. The document includes regulations on organization of preventive care centers and departments (offices), accounting and reporting forms, and equipment list. Earlier, on 12.09.97, the Order No. 270 was adopted on Measures of Population-Oriented Oncological Assistance Organization in the Russian Federation, focused on mass regular examination of population in an exam room settings. Features of this outpatient polyclinic medical organization unit were articulated in 2010 guidelines⁵.⁶. At the extended meeting of the Board of the Ministry of Health and Social Development, Minister Golikova T.V. announced within the framework of 2008 Ministry Performance Results and 2009 Objectives Agenda the opening of health centers, the key structures in prevention system organization. On August 19, 2009, the Ministry of Health and Social Development made an Order No. 597n on Managing of Healthy Lifestyle Promotion among Citizens of the Russian Federation in Health Centers, including Reduction of Alcohol and Tobacco Consumption. This Order undergone several revisions (Order of the Ministry of Health and Social Development No. 430, dated 06.06.2010; Order of the Ministry of Health and Social Development No. 328n, dated April 19, 2011; Order of the Ministry of Health and Social Development No. 1074, dated September 26, 2011; Order of the Ministry of Health and Social Development No. 683, dated September 30, 2015)⁹-¹⁰. First methodological recommendations on providing medical care to adults in health centers came out at the federal level only in 2012, on providing medical care to children – in 2017, although in some regions, this happened much earlier¹¹-¹⁴. In the Federal Law 323-FZ on the Fundamentals of Health Protection in the Russian Federation, dated 11/21/2011, one of the major principles was the prevention priority initiating the revival of mass screening surveys (screening examination/preventive medical examination) for early detection of chronic NCDs and their risk factors¹⁵. Preventive medical examination procedure that was approved by the Order No. 1011n (December 6, 2012) remains relevant, while the screening examination procedure applied to certain adult groups was revised several times (Orders No. 1006n (December 3, 2012), No. 36an (February 3, 2015), No. 964n (December 9, 2016)). At present, screening examination procedure is binded by the Order of the Ministry of Health of the Russian Federation No. 869n, dated 26.10.2017⁵.¹⁶.

In recent years, there have emerged new international sources of generalized data on chronic NCD prevention that cannot be ignored, like the 2016 European Guidelines on CVD Prevention, the Second Edition of TNM Staging Atlas, WHO and Russian Guidelines on Primary Cancer Prevention, and updates to USPSTF Recommendations, and to Recommendations on Screening for COPD, Cancer, Diabetes and other chronic diseases⁷-¹⁸.

**Ethical Clearance:** This study was approved by ethics committee of Irkutsk state medical university, Irkutsk, Russia.

**Results and discussion**

Methodical recommendations on screening were on a regular basis. They were attached to each edition of orders with the latest edition published in 2017. On December 21, 2012, the Order was made on the regular check-ups Procedure¹⁴. Even though the structure and volume of medical screening interventions changed significantly, accounting and reporting forms remained universal (Order of the Ministry of Health No. 87n of March 6, 2015), and those are forms #131/u and #131¹⁹. The Order No. 683n of September 30, 2015 on Approval of Organization and Implementation Procedures for
Non-Communicable Disease Prevention and Healthy Lifestyle Promotion in Medical Organizations was adopted to coordinate preventive activities for chronic NCD. However, it failed to create a system with delimitation of authority and withrelations between different prevention directions. General institutional problems that may affect the effectiveness of chronic NCD prevention programs are shown in Figure 1.

![Figure 1. Some General Institutional Problems in Chronic NCD Prevention](image)

Below are details on every single problem from Figure 1, evidence on problem relevance, negative consequences, and solutions.

**Problem I. Poor correlation between changes in regulatory documents**

**Case 1.**

Under the Order of the Ministry of Health of the Russian Federation No. 869n of 26.10.2017, some phase I tests were excluded from NCD screening, namely complete blood count, biochemical blood test, common urine test, ultrasound examination of abdominal and small pelvis, ultrasound examination of abdominal aorta. New added was a definition of prostate-specific antigen (PSA) in blood (for men aged 45 and 51). Consulting service was distinguished as short-term and individual prophylactic consulting. Phase II screening process was shortened by the exclusion of esophagogastroduodenoscopy, sigmoidoscopy, lipid, and glycated hemoglobin tests. Statistical reporting forms, approved by the Order of the Ministry of Health No. 869n on October 26, 2017. Nevertheless, the Order of the Ministry of Health No. 455 of September 23, 2003, is still in power, limiting diagnostic capabilities of those facilities to behavioral NCD detection.

**Case 2.**

Preventive care facilities were given more functions under the Order of the Ministry of Health of the Russian Federation No. 683n of September 30, 2015 (Appendix 1). Paragraphs 2, 4, and 6 that are devoted to screening/preventive health examinations were detailed by the Order of the Ministry of Health No. 869n on October 26, 2017. Nevertheless, the Order of the Ministry of Health No. 455 of September 23, 2003, is still in power, limiting diagnostic capabilities of those facilities to behavioral NCD detection. Medical prevention record book for medical treatment and preventive care facilities(Appendix 4, Form N 038/u-02), approved by the same Order, provides general information on public health events and health schools, but not on other activities.

**Negative consequences**

1. Reduced control capabilities;
2. Data falsification and fabrication;
3. Formal nature of preventive performance;
4. Lots of useless information that is not related to NDT prevention, but is there to overload primary care physician.

**Possible solutions**

1. Any significant change made in regulations on subdivisions should be accompanied by corresponding changes in accounting and reporting forms, control tools and methodological explanations of form filling procedure;
2. If a certain type of medical activity is regulated by several regulatory documents at once, change made in one of them should trigger the revision of rest documents involved.

**Problem II. Incomplete allowance for international experience and guidelines**

**Case 1.**

Population-oriented screening examination is an expensive service, so the reason for conducting such must be good from clinical and economic points of view. The most recognised approach to selecting examination methods is the European approach, known as the evidence-based medicine approach, and the USPSTF recommendations.
The first implies the definition of how intervention should be performed and to what extent, while the second centers around risk-benefit ratio. In Russia, incomplete allowance for international experience resulted in high screening costs that have been so for five years. Despite a significant number of interventions taken off the list in 2018, some items there are still to question.1, 16

Case 2
Health centers were created to promote healthy lifestyle among citizens of the Russian Federation, and to reduce alcohol and tobacco consumption. From this goal, objectives arose with the following majors: shaping of a responsible attitude to health, identifying and eliminating of NCD risk factors, and chronic NCD prevention. Units similar to these were created in other countries to prevent chronic NCDs from development on a national level. These units operated effectively due to minimal costs of risk factor assessment and elimination processes oriented on the population. This effectiveness was evidenced from a decline in chronic NCD incidence/mortality rates. In health centers, about 90% of time goes for determining functional changes, but their effect on chronic NCD incidence/mortality rates was not proven. Therefore, one can witness a featherbedding practice: equipment standards encompass hardware and software packages for psycho-physiological and somatic health screening, for assessing functional and adaptive reserves of the human body. Their use takes too much time, as well as the use of computerized heart disease screeningsystems, angiological screening systems, bio-impedancemetry systems; pulse oximetry systems; exhaled carbon monoxide analyzer kits; spirometers; blood and urine test kits used to detect cotinine and other markers (narcotic drugs); dental hygienist and optometrist equipment, which are also in equipment standards. Even spirometry is not recommended for asymptomatic citizens as a screening method.14, 18, 21. Despite the elimination of blood and urine cotinine/drug tests, executed by the Order of the Ministry of Health No. 683n on September 30, 2015, equipment standard intended for health centers was expanded with an ultrasonic densitometer.20

Negative consequences
1. Shift of emphasis from socially significant NDTs to secondary issues;
2. Irrational use of health care resources;
3. Failure of health centers to fight against chronic NCDs and their risk factors.

Possible solutions
1. Analysis and use of best experience in the fight against chronic NCDs;
2. Adherence to WHO recommendations on defining screening and mass screening strategies;22
3. Performing specific selection of interventions under evidence-based medicine and USPSTF approaches that are based on scientific review data and meta-analyses;
4. Error analysis and critical attitude towards them.

Problem III. Poor coordination and uneven assignment of responsibilities

Case 1
According to the Annex 1 of the Order of the Ministry of Health and Social Development No. 597n of August 19, 2009, any citizen who applied to the health center can have a complete examination once a year. The Order No. 683n, of September 30, 2015 revoked this provision, but new visit frequency indications were not made, so by default, a person can undergo complete examination in a health center 3 times within 3 years range. Those 18 years and older, except certain groups, get screened once in 3 years. Women aged 50 to 70 years, as well as both sexes at the age between 49 and 73, get screened twice a year. But according to the current Order No. 1011n of December 6, 2012, complete medical examination is done once every 2 years, excluding the year when screening survey is performed. On the face of such inconsistency of orders, this can only give rise to disorder. From the Order No. 869n of October 26, 2017, it is not clear whether screening replaces complete medical examination if screening is carried out two times in three years. For prevention and early detection of cancer, women 18 years and older, as well as men 30 years and older, suppose to make a visit to the exam room every 2 and 3 years, respectively. Thus, a person can apply to medical organization for NCD prevention 7–9 times in three years (2-3 times a year), but some examination methods will be used on him/her more than one time.1, 5, 7, 16, 20

Case 2
Organizing screening and complete medical examinations is one of the main functions that preventive care facilities have. However, according to the Order No. 869n of 8/16/2017, head physician is the only person responsible for their overall organization, responsibilities of medical personnel were not specified. This document does not secure the coordination of biological sampling, laboratory and instrumental surveys, and consultations of screening specialists to anybody either.
Negative consequences
1. Irrational use of resources plus higher loads on primary care physicians, who will be obligated to solve problems that can be solved in a centralized way;
2. Uneven population coverage;
3. Inadequate organization of patient flow;
4. Failure to meet deadlines, volume and quality of chronic NCD prevention services.
Possible solutions
1. Blending of health centers and preventive care facilities in medical organizationsto which health centers are attached; refusal from research methods that do not have evidential effect.
2. Enhancing the role of preventive care facilities, assigning new functions to them, like coordination of screening/preventive health examinations, screening program planning; capturing of attention among the population and explaining the screening procedure to it; establishing of relationships between units involved in screening/preventive health examinations; population flow organization.
3. Opening of exam rooms in preventive care facilities that would ensure early detection of precancerous and cancer changes that can be detected visually or via palpation; opening of medical care assistance office for those, who quits smoking.
4. Revising of regulatory documents governing NCD prevention to correct unnecessary duplicate interventions and to bring their provision frequency to that indicated in international recommendations.
5. Introducing of performance criteria for preventive care facilities; making sure those criteria are implemented.
Problem IV. Shift in emphasis to secondary prevention
Case 1
In countries that stuck to three strategies of chronic NCD prevention, NCD mortality rate dropped by more that 50%. Population-oriented strategy suggests an impact on 100% of the population. With 10% of money allocated for mortality reduction spent on chronic NCD prevention, NCD mortality will reduce by 25%. Screening/preventive health examinations provide an opportunity to attract health group I people that are at high risk of NCD development. Initially, these individuals were deprived of individual and/or group in-depth preventive consulting, which may act not only as an information-providing tool, but also as a motivator to change behavior and live a healthy life while the NCD risk is still low. According to the Orders No. 1006n (03.12.2012) and No. 36an (03.02.2015), health group II citizens sat high NCD risk and at very high risk of absolute total cardiovascular disease development have the opportunity to get individual and/or group screening consulting. The Order of the Ministry of Health No. 869n of 26.10.2017 obligated referral of these categories of people, as well as patients with obesity, total cholesterol of ≥8 mmol/L, and smokers that take over 20 cigarettes per day, to individual preventive consulting in preventive care facilities. This approach is ineffective because patients that do not have any symptoms have poor adherence to further therapy and preventive interventions, so the follow-ups minimal. Since screening/preventive health examinations are part of a high-risk strategy, health group II people are the target group. Proportion of the population at high NCD risk above 20%, and the contribution to mortality reduction via rational chronic NCD prevention is also estimated as 20%.
Case 2
Individual and/or group preventive consulting is provided for IIIa and IIIb health groups by Order of the Ministry of Health No. 869n of October 26, 2017 No. 869n, but it has to do nothing with screening, since elimination of risk factors in this case requires additional examination and depends on the nosological form and stage of disease, its severity. According to Russian classification: Group I citizens are citizens with no evidence of chronic NCDs (pathological conditions), which are the main cause of disability and premature mortality, and with no NCD risk factors, or these risk factors may be present at low/moderate total CVD risk and that do not require regular follow-up for other diseases (conditions). This category of citizens go through brief preventive consulting, and visit primary care physicians, medical doctors, or assistants, in preventice care offices and/or health centers for managing risk factors. Group II citizens are citizens with no evidence of chronic NCDs (pathological conditions), which are the main cause of disability and premature mortality, but do have NCD risk factors and high, or very high, risk of developing CVD. Thus, they need to be check-upped on a regular basis. This category of citizens have their risk factors corrected in preventice care offices and/or health centers. If necessary, medicine is indicated for this purpose. Group III citizens are citizens that have diseases requiring regular check-
ups or even special high-tech care. Citizens with suspected disease that would require extra tests are also the case, though their group may change after those tests. Such citizens have to check-up in primary care physician and other expert doctors, passing through treatment, recovery and prevention stages of healthcare.

The same applies to older people aged ≥75, who may get preventive treatment for senile asthenia at regular check-ups. Their count is insignificant compared with health group II people, but still time consuming.

Negative consequences
1. Lost opportunity to correct risk factors of chronic NCDs and to motivate health group I citizens for healthy living (population-oriented strategy);
2. Lost opportunity to correct risk factors of chronic NCDs and to motivate health group II citizens for healthy living (high-risk strategy);
3. Harm is possible if recommendations on eliminating risk factors given to IIIa and IIIb health groups were inadequate.

Possible solutions
1. Providing mandatory individual and/or group in-depth consulting as the most effective way of motivating I and II health groups for healthy living;
2. Ensuring the provision of IIIa and IIIb health groups, as well as patients at age ≥ 75, with mandatory individual and/or group in-depth consulting carried out as part of screening and ordinary visits.

Problem VI. Throw of efforts mainly on cardiovascular prophylaxis
Case 1
Cancer detection algorithms, approved by the Ministry of Health of the Russian Federation in 2009, are applied in screening/preventive health examinations on extremely rare basis. According to the Order of the Ministry of Health No. 869n of October 26, 2017, therapists examine only skin, but exam rooms provide a broader range of interventions for detecting pretumor and oncological changes in organs that can be detected visually or via palpation

Case 2
A number of essential risk factors for oncological diseases are not considered, but they, as well as other common risk factors for CVD, make a significant contribution to morbidity and mortality. These factors are communicable diseases, ultraviolet radiation, ionizing radiation, reproductive and hormonal factors, environmental pollution, and occupational exposure

Case 3
The algorithm for detecting diabetes does not involve the FINDRISK scale, which allows assessing the risk of diabetes development and reducing the extent of clarification examination

Negative consequences
1. Late identification of cancer located in organs that could be visually or via palpation;
2. No hyperglycemia and diabetes cases identified, due to mean sensitivity of fasting plasma glucose and glycated hemoglobin that were 0.25 and 0.49, respectively;
3. Diagnosis of diabetes and hyperglycemia will cost more.

Possible solutions
1. Getting exam rooms involved in screening/preventive health examinations;
2. Introducing of questionnaire that include questions associated with cancer risk factors;
3. Applying of FINDRISK score scale in screening/preventive routine to boost diagnostics and patient motivation for preventing hypertension and diabetes.

Problem VII. Poor automation
Case 1
Most health centers are still not connected to the Federal Information Resource (videoconferencing protocol No. 1/14/1). Moreover, FK ‘Health Center’ program is not installed on their computers.
Case 2
Screening/preventive health examinations are neither automated, nor connected to a unified information resource. The only option provided is the on-line questioning on the National Medical Research Center for Preventive Medicine website, section For Specialists/Screening Services for Adults/SADIP 3.0, or at http://sadip.ru/Patients/.

Negative consequences
1. High percentages of time spent on record maintenance, on search for information, and on calculations;
2. Errors in accounting and reporting forms, generated by mismatches or data transfer losses;
3. Real-time control over screening/preventive health examinations is impossible;
4. No centralized database, so epidemiological data cannot be used for reference;
5. People are divided into 27 group by age. This results in statistical distortion.

Possible solutions
1. Creating of a unified software that would allow automating and centralizing screening/preventive health examinations with file maintenance. This software can be made from technologies that are in common use in other industries, where they give good results;
2. Apply universal screening with different methods of automatic ranking, for example, by month of birth: 18 years, 1-4 months; 19 years, 5-8 months; 20 years, 9-12 months, etc.

Conclusion
Even though Russian Federation put a lot of effort in population health improvement within the past year, some general problems remain. Once they are solved, measures aimed at the prevention of chronic NCDs and elimination of associated risk factors can be significantly improved in terms of effectiveness. Despite a range of strategic measures undertaken, this research shows that the existing concept of chronic NCD prevention does not involve complete mechanisms for solving given problem. This necessitated the revision of regulatory documents for conifirmity with one another and with Russian and international clinical guidelines. The untimely emergence of organizational and methodological support become an obstacle to a unified coordination of preventive measures in practice. So far, their effectiveness was reduced.

Nevertheless, objective organizational difficulties and subjective factors generated by inadequate fulfillment of requirements imposed by regulatory documents, as well as new screening procedure implementation experience of the first years, did not hinder the government from doing a significant job. New screening procedure implementation experience put on display that methodological and organizational problems should be solved in order to improve the quality of screening and to achieve real outcomes. Screening quality is not the only case; solutions together with an effective regular check-ups organization will allow bring a real preventive component to the practice of providing medical services. This is the only practice that will reduce the number of exacerbation-related visits.

Conflict of interests
The authors declare no conflict of interests.

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