

Strategies for renal health: a project of the Spanish Society of Nephrology

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SCOPE AND OBJECTIVES OF A RENAL HEALTH PROGRAMME

Directed to all people living in Spain: individuals, risk groups and general population. The final goal is to improve renal health through the development of activities for promotion, health education, prevention, diagnosis, treatment and rehabilitation, oriented toward particular individuals, specific groups and the general population. The specific objectives are as follows: 1) increasing detection of CKD; 2) decreasing progression of CKD and associated cardiovascular morbidity and mortality; 3) decreasing iatrogeny due to contraindicated drugs or drugs used at an inappropriate dosing for the degree of kidney failure; and 4) reducing health care costs associated with the disease.

STRATEGIES

This Renal Health Plan includes four basic strategic areas: **Strategic area 1:** primary prevention in at-risk CKD patients. **Strategic area 2:** care of the patient diagnosed with CKD. **Strategic area 3:** training and research. Oriented towards the health professional and all groups involved with CKD. **Strategic area 4:** communication and spreading of information. Oriented towards the general population and especially towards the healthy individual and health professional.

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Strategies involve programmes and actions with Primary Care, patients, education at Undergraduate and Postgraduate levels of Medicine-Nephrology, collaboration with Scientific Societies, involvement with the Ministry of Health and Autonomous Communities, with Nursing Nephrology and Media Communications. All of this, the objective of this ambitious plan, will be with, because of and for the kidney patient.

INTRODUCTION

Chronic Kidney Disease (CKD) is defined as a decrease in kidney function, expressed by Glomerular Filtration (GF) estimated as $< 60\text{ml/min/1.73m}^2$ or as the presence of persistent kidney damage (proteinuria, alterations in urine sediment or in tests showing kidney image) for at least three months.¹ CKD is recognized as a worldwide public health problem² which affects approximately 10% of the population. It is underdiagnosed, has significant morbidity and has an independent cardiovascular risk factor. CKD is treatable and potentially preventable. Additionally, presence of CKD complicates the evolution of any vascular event, and as the GF measurement decreases, prognosis of patients worsens, causing a higher rate of hospitalizations, cardiovascular complications and mortality.³ Regarding dialysis patients, their mortality is 500 times higher than the population with normal kidney function. Furthermore, the presence of albuminuria, independent from GF, has shown to be another important cardiovascular risk factor.⁴

The CKD patient should be considered as having high vascular risk, as recognized by the most recent guidelines for treating arterial hypertension from the European Society of

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Hypertension and the European Society of Cardiology.⁵ This vascular risk may be modified by early intervention of mechanisms of the kidney disease's progression and with adequately controlled stricter treatment goals for arterial hypertension, reduction of albuminuria, strict metabolic control of glucose in diabetics, giving up smoking, avoiding being overweight and controlling dyslipidemia, among others.

In 2006, the International Society of Nephrology decided to alert professionals, health committees, patients and the general population of this problem through an annual celebration day called World Kidney Day, taking place in March. On this day, the message is sent out that CKD is common, often silent, very harmful and potentially treatable.⁶

The social, health and economic significance of CKD is only known because of the impact of replacement therapy for kidney functioning (dialysis or transplant), but there are studies regarding the K/DOQI stage 3-4 CKD patient showing that patients with lower GF have higher hospitalization costs.⁷

In October 2006, the KDIGO Organization (Kidney Disease: Improving Global Outcomes), published a document containing a series of recommendations which should be adopted worldwide in order to confront the problem of CKD in a rational way. The most highlighted ones are the following:²

- Governments must adopt a health policy regarding CKD, working closely together with non-governmental organizations and private industries (at the regional, national and international level.) CKD should be incorporated into Public Health programmes.
- Governments must support and fund programmes for the early diagnosis and follow-up of CRD including prevalence, incidence, evolution, care and education.

Thus, a renal health strategy for making professionals aware should be promoted, a strategy for renal health must be implemented which will effectively make healthcare professionals, patients and the general public acutely aware of the importance of being knowledgeable about kidney function, given the potential therapeutic and prognostic implications resulting from the early detection of this illness. Adequate knowledge and establishment of measures in these stages by the primary care doctor, is a treatment foundation of the renal health project.

In Spain, a benefit from collaboration between the Spanish Society of Clinical Chemistry, the Spanish Society of Family and Community Medicine and the Spanish Society of Nephrology has been the Consensus Documents published which provide unified and concisely defined criteria, estimation methods of kidney function and the referral of

patients to Nephrology, and the combined-effort treatment of these patients and the prevention of renal and neurotoxicity complications.^{8,9} These documents are a tool incorporated into the renal health plan which helps to promote optimal treatment for CKD patients in the Spanish National Health System and will simplify standardization between the areas of Primary and Specialized care.

CHRONIC KIDNEY DISEASE IN SPAIN. DATA FROM THE EPIRCE STUDY AND OTHER STUDIES FROM THE SPANISH SOCIETY OF NEPHROLOGY

Through its Strategic Action group, the Spanish Society of Nephrology has set a series of epidemiological studies in motion, some of which have already finished, which have provided clear definitions of the reality of CKD in Spain and its significance both in ambulatory care and in the hospital.¹⁰

EPIRCE (Epidemiology of Chronic Kidney Disease in Spain): transversal and descriptive epidemiological study of a population cohort which has shown that: 9.16% of the Spanish population has CKD, with a GF < 60ml/min/1.73m² detected in 6.8%, and 21.7% for those 65 years or over.

EROCAP (Silent Kidney Disease in Primary Care Centres):¹¹ transversal multi-centre epidemiological study of a population treated in Primary Care Centres, which detected a CKD stages 3-5 prevalence of 21.3%. In patients of over 70 years, this prevalence increased to 33.7%. It should be highlighted that of the patients with a GF < 60ml/min, 37.3% had serum creatinine levels (SCr) in the laboratory normalcy range (silent kidney disease). This problem was found mainly in women.

PIER: incident patients with kidney disease in Nephrology Units of Spain. Epidemiological, multi-centre, transversal and descriptive study to find the degree of CKD in patients arriving to the Nephrology Department through referral to outside consultation or Emergency services. Of these, 65.8% had kidney failure (CKD stage 3, 39.5%; stage 4, 19.2%; stage 5, 7.1%). The majority of patients were sent from Primary Care (61.1%).

MERENA: morbidity and mortality in kidney disease in two cohorts of diabetic and non-diabetic adult patients with kidney failure, who were followed up by Nephrology consultations for five years. 1,129 patients were included, and the study finished in April 2009. The study shows high morbidity and mortality in CKD patients, with greater frequency in diabetics and stage 4 CKD patients.

ERPHOS (preliminary data pending validation): assessment of kidney disease in the Spanish population admitted to hospitals. Epidemiological, multi-centre, transversal and descriptive study. 14,785 patients were included, 28.4% of

which had GF < 60ml/min, 13.1% had GF < 44ml/min, and for those over 80 years, prevalence of GF < 60ml/min was 42% in men and 59% in women.

GERTRA (preliminary data pending validation): degree of kidney disease in kidney transplant patients. 2,192 patients were included, 67% of which showed GF < 60ml/min (50.8% in stage 3, 13.9% in stage 4 and 2.3% in stage 5).

In addition, other studies have been carried out which focus on specific complications such as alterations of bone-mineral metabolism and anaemia.

Prevalence of kidney failure increases progressively with aging (22% for those over 64 years, 40% for those over 80), and also with other pathologies such as type 2 diabetes, arterial hypertension and arteriosclerosis. The majority of patients with kidney failure have not been diagnosed, especially women, for whom the inefficiency of traditional measurement methods of kidney function (serum creatinine) becomes quite relevant for diagnosing kidney failure. Kidney failure patients usually have elevated vascular risk, with significant morbidity and mortality in follow-ups and are usually sent late to Nephrology Units.

IMPORTANCE OF EARLY DETECTION OF CHRONIC KIDNEY DISEASE

Data from the EPIRCE study confirm that about 4 million people have CKD in Spain, and of these, more than half may have kidney failure at less than 60ml/min/1.73m². Currently, about 50,000 patients are in kidney replacement therapy. Half are in dialysis, and the rest have a functioning kidney transplant. This number increases 4% each year, which implies a very high social and economic cost.

However, it seems apparent that not all patients with CKD will progress into needing dialysis or a transplant. International studies and data in Spain from the MERENA study confirm that CKD is a significant vascular risk factor, and many of these patients will die from vascular causes before attaining kidney replacement therapy.^{3,12} Early identification of these patients allows for long-term morbidity and mortality improvement and decreases costs for both the patient and health system. Reduced costs derive from early identification of reversible causes of kidney failure, reduced speed of kidney disease's progress, reduced associated cardiovascular morbidity and mortality and, in the case of advanced kidney disease (stages 4 and 5), the patient's adequate preparation for Renal Replacement Therapy (RRT).

Other patients, especially those of advanced age, can avoid advanced stages if correctly treated comprehensively and pharmacologically, avoiding drug iatrogenia.

A recent meta-analysis studying mortality and hospitalizations of advanced CKD patients who were sent early or late to Nephrology Units and which included 12,749 patients, showed a higher risk of mortality (RR: 1.99) and more hospitalization days (12 days on average) for patients sent late.¹³

Therefore, it is necessary to identify the population at risk of developing CKD, which could benefit from a screening through simple analytical tests. The at-risk population included people over 55 years, hypertensive or diabetic patients, those with antecedents of a cardiovascular event, or family members of kidney patients. There are a few screening programmes which are both for the general and selected population, and the most efficient programme is yet to be decided considering available health resources and characteristics of the population to be evaluated. A study in an American population without hypertension or diabetes has shown that the screening is cost-effective from 60 years onward (\$53,372 per QALY saved). For hypertensive patients, cost-effectiveness is much greater, even if the study is done from 30 years onward (\$26,320 per QALY saved). In the programme of albuminuria detection of the entire Dutch population, the calculated cost was €16,700 for each year of life saved.¹⁴⁻¹⁶

Initiatives should be established which increase health professionals and the general population's awareness of the frequency and importance of early CKD detection. Awareness is especially important among Primary Care doctors, and especially when there are various circumstances which are of great interest and are related to CKD, and these are normally not taken into account at the time of assessing cost-effectiveness of early detection.

DRUGS AND CHRONIC KIDNEY DISEASE

In daily clinical practice, the prescription of renal elimination drugs commonly occurs without knowing the patient's GF, and therefore, without adjusting based on GF, and this causes a risk adverse side effects due to overdosing. Furthermore, there are nephrotoxic drugs which should be avoided in kidney failure treatment. Generalized use of estimated GF through formulas provides the clinic with a simple method for identifying and stratifying CKD patients, and at the same time, deciding the most suitable prescription for treatment. This is especially important for the population over 65 years, which is also the most polymedicated. At this important stage in avoiding iatrogenia, we should consider the drugs which act on the renin-angiotensin system (ACEI, ARA II, aliskiren), NSAID, potassium sparing diuretics, some oral hypoglycemics and iodine contrast agents, among others.

SIGNIFICANCE OF CHRONIC KIDNEY DISEASE IN THE ELDERLY POPULATION. LIMITATIONS OF THE ESTIMATION OF GLOMERULAR FILTRATION

Epidemiological studies have shown a clear relationship between GF reduction and age. For all ages, there is increased mortality risk as GF decreases below 60ml/min, except for those over 75 years and for those for whom risk becomes significant only below 45ml/min (CKD stage 3b).¹⁹

However, interpretation of estimation of GF through formulas derived from creatinine is not always simple in this population, especially in ranges close to normalcy limits. Interpreting low GF of an elder is a difficult dilemma. Autopsy studies have shown that kidney size and weight, and the number of nephrons decrease with age.¹⁷

There is a doubt whether the rate of renal deterioration corresponds with aging, in the absence of another marker such as albuminuria, and if it is a biological phenomenon associated with aging, for which no specific approach is needed to be taken, or if it should be taken into account because it could prevent greater deterioration through some approach or intervention. Some studies have questioned estimation of GF in elders, suggesting that it only contributes to an inadequate sending of elders to Nephrology consultation.¹⁸

One of the most important challenges in this respect is identifying those patients, including elders, with a reduced GF who may benefit from being sent to Nephrology. Probably, it is those patients who have significant albuminuria or progression of kidney failure. In the meantime, and although currently there is not enough evidence to establish that a person over 70-75 years, with a GF between 30 and 60ml/min, without albuminuria or persistent alterations in urine sediment, may have a kidney disease. This patient should at least be considered as having possible risk of iatrogenia due to inadequate drug dosing for kidney function or inadequate for patients with reduced GF. These patients should at least have monitoring of kidney function done by the Primary Care doctor.

With all of its limitations, the generalized use of estimated GF continues to be the main tool to monitor and make uniform the treatment of alterations in kidney function. It is hoped that shortly such limitations can be solved for optimal use of CKD diagnostic tests. This would lead to a strategy for optimal resources in treating CKD between Primary Care and Nephrology.

RENAL HEALTH PROGRAMME

The high prevalence of CKD coupled with its tendency to go undiagnosed during its early stages, and its progressive yet

modifiable nature make it necessary to put together, at the national level, a programme to facilitate the diagnosis of kidney disease in its early stages, in the hope of avoiding the subsequent development of related cardiovascular complications, progression of kidney disease, the inappropriate prescribing of medications and, as a last resort, to provide Nephrology specialists with a late reference which allows them to properly control complications associated with advanced CKD, prepare the patient with enough time in advance for the replacement techniques of kidney function (haemodialysis or peritoneal dialysis), to receive a kidney transplant prior to initiating dialysis treatments.

Existing programmes for renal health are similar and consist of determining control of arterial pressure in the at-risk population, a sample blood analysis (creatinine and estimation of GF) and an analysis of proteinuria in a simple sample of morning urine. Detection and confirmation of CKD presence requires a follow-up by the Primary Care doctor and by the specialist in Nephrology when necessary. This also involves the establishment of hygienic-dietary measures, advice on medications and pharmacological measures for preventing cardiovascular and kidney disease progression.

The programme for Renal Health should make all health professionals jointly responsible and especially doctors from Primary Care and Nephrology Departments from different Autonomous Communities (ACs). Indeed, to facilitate coordination among professionals, the Spanish Society of Nephrology and the Spanish Society of Family and Community Medicine have prepared a Consensus Document with recommendations for the detection, treatment and referral of patients with CKD.⁹

SCOPE OF STRATEGIES FOR RENAL HEALTH

Aimed at the entire Spanish population, especially at persons at risk of CKD, but including informative activities for the entire population. Such strategies should be developed as a continued and ongoing activity, and should be subjected to an overall evaluation process based on quality standards and attainment objectives, which are established by such a given process.

OBJECTIVES

The final goal is to improve renal health of the Spanish population through the development of activities for promotion, health education, prevention, diagnosis, treatment and rehabilitation, oriented toward particular individuals, specific groups and the general population.

The **specific objectives** are as follows: 1) increasing detection of CKD, as early as possible; 2) decreasing progression of CKD y associated cardiovascular morbidity and mortality; 3) decreasing iatrogeny due to contraindicated drugs or drugs used at an inappropriate dosage for the degree of kidney failure; and 4) reducing health care costs associated with the disease.

TARGET POPULATION FOR THE RENAL HEALTH PLAN

- **Individual:** directed towards particular individuals, normally through medical consultation.
- **Group:** oriented towards groups at risk of developing CKD or to groups of patients in different stages.
- **Population:** through preventative campaigns using media communications, with the objective of reaching the highest possible percentage of the population. The backers are Health Services and/or Scientific Societies and/or Associations of Patients.

STANDARDIZATION OF RENAL CARE

Implementation in all ACs of a standardized system for assessing estimated GF and albuminuria in the population at-risk of developing CKD is a key element for achieving the objectives of strategies for renal health. Therefore, introducing determinations of the presence of and degree of CKD in the Contract-Programme of Health Centres would allow professionals in charge of these patients' follow-up to more easily make decisions.

In each health area, the definition of consensus criteria of actions and referrals is necessary. The SEN-SEMFYC Consensus Document is a tool incorporated into the renal health plan which will simplify standardization between the areas of Primary and Specialized care. In many areas, modifications may be made to the Consensus Document, but it will serve as a reference basis for the entire national territory.

STRATEGIC AREAS

Strategic area 1: primary care prevention for at-risk CKD patients. Oriented toward the healthy individual or toward the individual with an antecedent indicating risk of CKD.

- Strategic objective: determining presence of CKD through laboratory exams in the at-risk population: serum creatinine and estimated GF through formulas and albumin in a simple sample of urine.
- Target population: over the age of 60, hypertension, diabetes, cardiovascular disease or kin of patients with kidney failure.

- Actions should include:
 - Making all health professionals aware of the importance of estimation of GF and proteinuria, and promoting adequate observance of this.
 - Providing tools which allow the professional to facilitate diagnosis of CKD: promoting that estimated GF appears alongside creatinine in laboratory reports and in clinical computer workstations, and promoting the detection of proteinuria in a simple sample of urine through a test strip and/or ideally quantifying the albumin-creatinine quotient in urine.
 - Providing suitable information for professionals on the importance of reduced GF in the population and the limitations it can have in the elderly population, especially in women.
 - Identifying warning signs in order to send the patient to Nephrology.
 - Developing continuing accredited education activities, oriented toward spreading knowledge about CKD among health professionals.
 - Explaining the meaning of CKD to the general population, associations of patients and to specific groups, such as parents, educators and professors, along with vulnerable population groups (people over 60 years or with arterial hypertension, diabetes mellitus, cardiovascular disease, antecedents of CKD in family).
 - Developing methodological guidelines for promotion and education of renal health, with the necessary adaptations for targeting the general public or at-risk groups.
 - Developing programmes for promotion and education of renal health and putting these in particular places (educational centres, residences of elders, etc.)

Strategic area 2: secondary care prevention: care of the patient diagnosed with CKD. Oriented towards the patient diagnosed with CKD at any stage.

- Strategic objective: reducing progression of CKD, its complications and vascular risk associated with CKD.
- Target population: all patients diagnosed with CKD at any stage.
- Actions:
 - Developing or adapting Clinical Practice Guidelines on actions for CKD and its dissemination to all involved professionals.
 - Developing or adapting Clinical Practice Guidelines related to suitable drug use in each stage of CKD.
 - Establishing consensus with different health professionals involved with CKD: Primary Health Care, Cardiology, Internal Medicine, Oncology, pharmaceuticals, etc., for the drafting of action and referral guidelines which allow for decreased variability in clinical practice, and optimize treatment of CKD patients.
 - Establishing indicators of the quality of care given and monitor the indicators.

- Carrying out workshops for training, promotion and education directed toward patients and their family members for the CKD patient's health. In the workshops, importance of controlling cardiovascular risk factors and controlling limitations in using particular types of drugs will be emphasized.

This is a foundational project which requires the development of educational aspects (meetings, conferences, interactive information systems, etc.) with health journalists specialized such that we may communicate the significance of CKD through them to the population, to doctors in general and to health personnel.

Strategic area 3: training and research. Oriented towards the health professional and towards all groups involved with CKD.

- Strategic objective: promoting education, teaching and research on CKD, detection and treatment for all professionals and groups involved with health and with kidney disease.
- Target population: Spanish health professionals and personnel in training (students, medical residents), along with all professionals who develop education projects for health.
- Actions:
 - Developing continuing education activities on the detection and treatment of CKD directed towards professionals in health and in involved social areas in treating kidney disease patients.
 - Developing specific activities at the undergraduate and postgraduate educational levels on CKD for medical students and resident doctors in training.
 - Developing educational activities oriented towards spreading the importance of strategies for renal health directed towards non-health professionals: communicators, teaching staff, professionals in social areas.
 - Promoting studies and research projects related to kidney disease:
 - Epidemiological studies on CKD prevalence, at risk population and rate of detection.
 - Studies on effectiveness of interventions for prevention and treatment.
 - Studies on cost-effectiveness of CKD detection in the at-risk population.
 - Collaboration agreements between different scientific Societies for the development of prospective studies on the evaluation of effectiveness and usefulness of proposed health care and organizational interventions.

Strategic area 4: communication and spreading of information. Oriented toward the general population and especially toward the healthy individual and health professional.

- Strategic objective: spreading information and making Strategies for Renal Health known within the community and to health professionals as being a consensus instrument of health professionals, which is a collection of the best methods for prevention and treatment of CKD.
- Target population: the entire Spanish population and all health professionals involved in the health care of that population.
- Actions:
 - Carrying out educational actions for professionals in media communications to promote awareness of the significance of CKD and its detection and prevention in the community.
 - Circulating strategies and their content through media communications, with defined and specific aspects for general media communications and media specialized in health.
 - Supporting the creation of informative slots on renal health in different media communications.
 - Designing a media campaign on health strategies through advertising messages and using specific content in different media communications, television, radio, press and internet.
 - Establishing agreements with social agents involved with CKD, and these being key, such as Associations of kidney patients, Health Institutions and the National Organization of Transplants.
 - Promoting the spreading of strategies and the participation of all groups involved with CKD in the annual day known as World Kidney Day.
 - Establishing communication methods so that the involved professionals may easily access information on strategies and on the compilation of their actions.

PROPOSED ACTIONS

1. **Actions with Primary Care:** the programme for renal health should be obligatorily coordinated between doctors from Primary Care and Nephrology Departments from different ACs. The objectives to be accomplished are principally educational and structure can be based on:
 - An online course for Primary Care on CKD.
 - Educational meetings between both Societies for the development of various programmes which include specific clinical aspects.
2. **Programme for patients:** coordinated with SEDEN and Associations of kidney patients, projects of education and message dissemination on the significance of chronic kidney disease, and especially its significance relating to family, will be carried out.

3. **Renal health and the University:** the University group of the SEN will function through courses, seminars, and on the undergraduate and postgraduate levels on the significance of CKG as a cardiovascular risk factor and the need for its early detection.
4. **Coordination with Scientific Societies:** with the objectives of implementing and spreading the importance of early knowledge and detection of CKD; these will put into motion or will continue educational projects with Scientific Societies related to kidney disease:
 - Spanish Society of Cardiology.
 - Spanish Society of Inpatient and Outpatient Pharmacy.
 - Spanish Society of Geriatrics.
 - Spanish Society of Family and Community Medicine (SEMFYC), Spanish Society of Rural and General Medicine (SEMERGEN), Spanish Society of General Medicine (SEMG).
 - Spanish Society of Internal Medicine.
 - Spanish Society of Oncology.
 - Spanish Society of Clinical Chemistry.
 - Spanish Society of Urology.

Also, any other Society who sees it fitting to be incorporated throughout development of the Renal Health Plan.

5. **Actions with the Ministry of Health and AC:** the EPIRCE study was carried out in conjunction with the Ministry of Health. Their results continue to move the programme toward the level of AC. Interviews will be promoted with Health Ministers from different AC for carrying out programmes in Educational Centres and especially programmes which focus on the rational use of medications. Actions will be channelled through the Regional Societies of Nephrology, the National Organization of Transplants and its Autonomous Coordinators, depending on logistical support of the Industry, which is indispensable for putting this into practice.
6. **Renal health and Nursing:** joint actions will be promoted with the SEDEN to advance the programme for renal health:
 - Actions in Conferences and Educational Courses.
 - Courses in Nursing Schools.
 - Programmes at the level of Primary Care Nursing.
7. **Renal health and media communications:** This is a foundational project which requires the development of educational aspects (meetings, conferences, interactive information systems, etc.) with health journalists specialized such that we can communicate the significance of CKD through them to the population, to the doctors in general and to health personnel.

FINANCING

The initiation of Strategies for Renal Health has until now depended on an unrestricted grant from AMGEN (the company which financed the nationwide EPIRCE study and the presentation of strategies for renal health on March 12, 2009 on World Kidney Day). Many other pharmaceutical companies related to dialysis have also supported both the general presentation of these strategies as specific actions and supported defined studies in the four Strategic Areas previously described. We would like to show our gratitude to Abbott, Amgen, Bellco, Fresenius, FRIAT, Novartis, Roche and Shire who have directly collaborated with organizing the 2009 World Kidney Day, and also to all organizations who are backing various studies and actions which are already underway or are about to begin.

Short and medium-term practical programme

- Meeting of the Strategic Action of SEN with an invitation to Societies and Organizations who are involved with CKD.
- Presentation of the programme in the General Administration of Quality of the National Health Service of the Ministry of Health with the organizing of a national conference to present epidemiological results from the EPIRCE study and present strategy design guidelines for Renal Health at the level of ACs.
- Definition of the coordinators of Primary Care and Nephrology at the level of each AC to develop the educational programme on Renal Health.
- A to-be-defined programme of an educational project on Renal Health for media communications.

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