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# Family Practice Forum

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## A Research Agenda for Family Physicians

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Family medicine has been the most rapidly growing sector in American medicine. In many medical schools, programs in family medicine, general medicine, and general pediatrics were established in response to an increasing desire and need of people for general physicians who would take continuing care of them and who know their families and circumstances. Family physicians and other primary care physicians have enriched American medicine. They often have located in areas of communities that had difficulty obtaining medical care, and they have developed practice styles less dependent on expensive hospital-based technology and ancillary services.

Medical school programs in family medicine, general medicine, and general pediatrics have begun to contribute significantly to the development of opportunities for training physicians in ambulatory care and community settings. This contribution to the training of physicians in primary care has had a salutary effect and has provided a focus on what had become a neglected area in medical education and in the clinical activity of medical faculty.

One area in which family medicine and other primary care physicians have had difficulty, how-

ever, is in identifying and developing an area of research that is their own and that adds a new dimension to medical knowledge. The predominant ambulatory or community settings in which primary care training programs in medical schools developed have understandably led to a heavy emphasis on studies dealing with educational methods, practice procedures or style, patient surveys, and patient and family behavior, with considerable emphasis on epidemiology and social science methodologies.

As the science base of medicine expanded, research, clinical practice, and education increased specialization. The study of science and knowledge by its very nature usually is reductionistic. Correspondingly, having and developing new knowledge about specific diseases and associated technology often lead to additional areas of specialization.

Family medicine, general medicine, and general pediatrics, however, represent programs that attempt to consolidate or reassemble specialized knowledge as it may apply to the care of patients, irrespective of the presence or nature of particular diseases. Such is the main thrust of general medical care. By definition, the term *general* means to be concerned with the universal or the whole rather than only particular aspects, concerned with main elements rather than limited details, and not confined by specialization. In a sense, general medical care has as its objective the maintenance or restoration of health, not only the diagnosis and treatment of a particular set of diseases. This statement is not meant to imply that physicians

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who provide specialized medical care are not concerned about the general health of their patients, but their objective is very much more directed toward the study, understanding, and control of disease. Such a focus contributes to people's health, but emphasizes the restoration of metabolic, anatomical, biochemical, or physiologic function as a step toward personal health.

If personal health is the objective of general medical care, it becomes very important for general physicians to define as precisely as possible what is meant by health. "Health, like happiness, cannot be defined in exact measurable terms because its presence is so largely a matter of subjective judgment. About as precise as one can get is that health is a relative affair that represents the degree to which an individual can operate with effectiveness within the particular circumstance of his heredity and his physical and cultural environment."<sup>1</sup> Using this definition, therefore, general physicians have as their objective helping people regain or maintain an optimal level of functional effectiveness in their lives within the constraints or limitations imposed by their heredity and physical and cultural circumstances.

Many variables can affect functional effectiveness in everyday life, including disease; native abilities; ethnic, religious, social, and cultural characteristics; wealth and poverty; age; family and social supports; climate and environment; emotional status; dependency; and heredity. Although not all of these variables are subject to change or interventions by physicians, effective adaptation to unchangeable constraints or limitations can be an important factor in maintaining or restoring a person's health. Physicians can intervene and eliminate some circumstances that impair lives, and they can help people adapt to unchangeable limitations in ways that enable them to live their lives more effectively. To do this, however, the physician must understand the determinants of functional ineffectiveness and understand the strategies that can maintain or improve functional effectiveness.

Investigation of the determinants of patients' functional ineffectiveness and evaluation of interventions that might improve their functional effectiveness are neglected areas in reductionistic medical science and specialized medical care, but these areas lie fully within the objectives and purposes of general physicians. They, after all, should

be most concerned about people's health or ability to operate effectively in their everyday lives irrespective of disease or circumstance. For general physicians to focus their attention and research on those actions or interventions that improve the quality of lives becomes, then, an important opportunity and challenge. It seems likely that with a focus on the functional effectiveness of patients, general physicians can make a contribution to enlarging the knowledge base of medical practice, establish their particular area of scientific expertise, and improve medical practice and patient outcomes.

Research on personal function is difficult. Although several instruments have been developed for measuring functional status, their applicability to the regular practice of medicine probably is limited.<sup>2</sup> Furthermore, regardless of how functional status is measured, the many variables affecting how effectively persons operate that must be assessed often require rigorous observational rather than randomized studies. Such studies may or may not focus on a particular disease. Many factors affecting personal function are not disease specific. The determinants of functional ineffectiveness or effectiveness may differ very little, if at all, in patients with amyotrophic lateral sclerosis, multiple sclerosis, paraplegia, hemiplegia, or other chronic neuromuscular disorders affecting mobility.

Similarly, the determinants of functional effectiveness or ineffectiveness of very old persons who have only the limitations associated with advancing age may not be attributable to a particular disease. The determinants of delay in convalescence or recovery from the asthenia associated with acute illnesses such as influenza, hepatitis, infectious mononucleosis, or even myocardial infarction may have less to do with the disease itself than with other factors that can affect functional status and personal responses to illness.<sup>3,4</sup>

Only clinicians can identify the problems that result in sickness or disability and are able to select for study the critical variables that should be investigated. Certainly they may need assistance from others in designing the studies to be done, just as those investigating the pathophysiology of disease may need assistance from biochemists and physiologists. But selection of the problems and the variables to be studied are best made by clinicians.

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**Azo Gantrisin®**

Each tablet contains 0.5 Gm sulfisoxazole/Roche and 50 mg phenazopyridine HCl.

Before prescribing, please consult complete product information, a summary of which follows:

**INDICATIONS:** Initial treatment of uncomplicated urinary tract infections caused by susceptible strains of *Escherichia coli*, *Klebsiella* species, *Enterobacter* species, *Proteus mirabilis*, *Proteus vulgaris* and *Staphylococcus aureus* when relief of pain, burning or urgency is needed during first 2 days of therapy. Azo Gantrisin treatment not to exceed 2 days. Evidence lacking that sulfisoxazole plus phenazopyridine HCl better than sulfisoxazole alone after 2 days. Treatment beyond 2 days should only be continued with Gantrisin (sulfisoxazole/Roche). (See DOSAGE AND ADMINISTRATION.) **Important Note:** Coordinate *in vitro* sulfonamide sensitivity tests with bacteriologic and clinical response. With ongoing therapy, add aminobenzoic acid to culture media. Increasing resistance of organisms may limit sulfonamide usefulness. As identical doses produce wide variations, measure blood levels in patients receiving sulfonamides for serious infections: 12 to 15 mg/100 ml is optimal; adverse reactions are more frequent above 20 mg/100 ml.

**CONTRAINDICATIONS:** Children under 12; known sensitivity to either component; pregnancy at term and during nursing period; in glomerulonephritis, severe hepatitis, uremia and pyelonephritis of pregnancy with gastrointestinal disturbances.

**WARNINGS:** Sulfonamides are bacteriostatic; organisms causing common infections are often resistant. Sulfas won't eradicate group A streptococci or prevent sequelae like rheumatic fever and glomerulonephritis. Deaths from hypersensitivity reactions, hepatocellular necrosis, agranulocytosis, aplastic anemia and other blood dyscrasias have been reported. Sore throat, fever, pallor, purpura or jaundice may be early signs of serious blood disorders. Perform blood counts and renal function tests.

**PRECAUTIONS:** *General:* Use with caution in patients with impaired renal or hepatic function, severe allergy, bronchial asthma. Hemolysis may occur in glucose-6-phosphate dehydrogenase-deficient individuals.

The more soluble sulfonamides are associated with fewer renal complications. Maintain adequate fluid intake to prevent crystalluria and stone formation.

*Information for Patients:* Maintain adequate fluid intake; urine will turn reddish-orange.

*Laboratory Tests:* Perform urinalysis with careful microscopic examination at least once a week and regular blood counts after 2 weeks therapy; measure blood levels in patients with serious infection (see INDICATIONS). *Drug Interactions:* Sulfonamides may displace oral anticoagulants from plasma protein binding sites, increasing anticoagulant effect. Can also displace methotrexate. *Drug Laboratory Test Interactions:* May affect liver function tests in hepatitis.

*Carcinogenesis, Mutagenesis, Impairment of Fertility:* **Carcinogenesis:** Azo Gantrisin has not undergone adequate trials relating to carcinogenicity; each component, however, has been evaluated separately. Rats appear especially susceptible to goitrogenic effects of sulfonamides; long-term administration has resulted in thyroid malignancies in this species.

Long-term administration of phenazopyridine HCl has induced neoplasia in rats (large intestine) and mice (liver). No association between phenazopyridine HCl and human neoplasia reported; adequate epidemiological studies have not been conducted. **Mutagenesis:** No studies available. **Impairment of Fertility:** The components of Azo Gantrisin have been evaluated in animal reproduction studies. In rats given 800 mg/kg/day sulfisoxazole, there were no effects on mating behavior, conception rate or fertility index. Fertility was not affected in a two-litter study of rats given 50 mg/kg/day phenazopyridine.

**Pregnancy: Teratogenic Effects:** Pregnancy Category C. The components of Azo Gantrisin have been evaluated. At 800 mg/kg/day sulfisoxazole was nonteratogenic in rats and rabbits, with no perinatal or postnatal effects in rats. In two other studies, cleft palates developed in rats and mice after 500 to 1000 mg/kg/day sulfisoxazole. No congenital malformations developed in rats given 50 mg/kg/day phenazopyridine. As there are no satisfactory animal or human studies, it is not known whether Azo Gantrisin can cause fetal harm or affect reproduction capacity. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nonteratogenic Effects, Nursing Mothers and Pediatric Use:** See CONTRAINDICATIONS.

**ADVERSE REACTIONS:** **Allergic:** Anaphylaxis, generalized allergic reactions, angioneurotic edema, arteritis and vasculitis, myocarditis, serum sickness, conjunctival and scleral injection, periarteritis nodosa, systemic lupus erythematosus. **Cardiovascular:** Tachycardia, palpitations, syncope, cyanosis. **Dermatologic:** Rash, urticaria, pruritus, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, photosensitivity. **Endocrine:** Goiter production, diuresis, hypoglycemia. Cross-sensitivity with some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents may exist. **Gastrointestinal:** Nausea, emesis, abdominal pain, anorexia, diarrhea, glossitis, stomatitis, flatulence, salivary gland enlargement, G.I. hemorrhage, pseudomembranous enterocolitis, melena, pancreatitis, hepatic dysfunction, jaundice, hepatocellular necrosis. **Genitourinary:** Crystalluria, hematuria, BUN and creatinine elevation, nephritis and toxic nephrosis with oliguria and anuria, acute renal failure, urinary retention. **Hematologic:** Leukopenia, agranulocytosis, aplastic anemia, thrombocytopenia, purpura, hemolytic anemia, anemia, eosinophilia, clotting disorders including hypoprothrombinemia and hypofibrinogenemia, sulfhemoglobinemia, methemoglobinemia. **Musculoskeletal:** Arthralgia, chest pain, myalgia. **Neurologic:** Headache, dizziness, peripheral neuritis, paresthesia, convulsions, tinnitus, vertigo, ataxia, intracranial hypertension. **Psychiatric:** Psychosis, hallucinations, disorientation, depression, anxiety. **Miscellaneous:** Edema (including periorbital), pyrexia, drowsiness, weakness, fatigue, lassitude, rigors, flushing, hearing loss, insomnia, pneumonitis.

**OVERDOSAGE:** **Signs:** Anorexia, colic, nausea, vomiting, dizziness, drowsiness, unconsciousness; possibly pyrexia, hematuria, crystalluria. Blood dyscrasias and jaundice may occur later. **Treatment:** Institute gastric lavage or emesis; force oral fluids; administer intravenous fluids if urine output is low with normal renal function. Monitor blood counts and appropriate blood chemistries, including electrolytes. In cyanosis, consider methemoglobinemia and treat with intravenous 1% methylene blue. Institute specific therapy for blood dyscrasias or jaundice.

**DOSAGE AND ADMINISTRATION:** Azo Gantrisin is intended for the acute, painful phase of urinary tract infections. The recommended dosage in adults is 4 to 6 tablets initially, followed by 2 tablets four times daily for up to 2 days. Treatment with Azo Gantrisin should not exceed 2 days. Treatment beyond 2 days should only be continued with Gantrisin (sulfisoxazole/Roche).

**HOW SUPPLIED:** Tablets, each containing 0.5 Gm sulfisoxazole/Roche and 50 mg phenazopyridine HCl—bottles of 100 and 500.



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General physicians are in the best position to evaluate interventions that might improve or maintain function or prevent functional deterioration, and these interventions need not be only the application of particular medical technologies used to treat particular diseases. In fact, the intervention could be a modified system of care including provision of human support, counseling, change in environment, or other nontechnological forms of care in addition to technology.

Functional effectiveness is not a static, but a kinetic process. Studies of function, therefore, often will require continuous care and observation of patients over long periods of time. In fact, there is a great need for research, new knowledge, and understanding of functional outcomes. General physicians, who provide most continuing care to patients, are therefore in a good position to develop information on prognostic determinants of patient functional status. If medicine is ever to intervene in ways other than the care of acute and episodic disease or illness, physicians must be able to predict functional outcomes and evaluate the effect of their interventions on these outcomes.

These comments are not meant to diminish or negate other investigations by academic general physicians. They are presented to indicate what I perceive as logical, rational, meaningful, and special ways these academic general physicians can add significantly to present medical knowledge, establish for themselves a special research objective, and contribute to patient care.

## References

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