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Strategies for Implementing the New International Health Regulations in Federal Countries

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Strategies for implementing the new International Health Regulations in federal countries

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Abstract The International Health Regulations (IHR), the principal legal instrument guiding the international management of public health emergencies, have recently undergone an extensive revision process. The revised regulations, referred to as the IHR (2005), were unanimously approved in May 2005 by all Member States of the World Health Assembly (WHA) and came into effect on 15 June 2007. The IHR (2005) reflect a modernization of the international community's approach to public health and an acknowledgement of the importance of establishing an effective international strategy to manage emergencies that threaten global health security.

The success of the IHR as a new approach to combating such threats will ultimately be determined by the ability of countries to live up to the obligations they assumed in approving the new international strategy. However, doing so may be particularly challenging for decentralized countries, specifically those with federal systems of government. Although the IHR (2005) are the product of an agreement among national governments, they cover a wide range of matters, some of which may not fall fully under the constitutional jurisdiction of the national government within many federations. This tension between the separation of powers within federal systems of government and the requirements of an evolving global public health governance regime may undermine national efforts towards compliance and could ultimately jeopardize the regime's success.

We hosted a workshop to examine how federal countries could address some of the challenges they may face in implementing the IHR (2005). We present here a series of recommendations, synthesized from the workshop proceedings, on strategies that these countries might pursue to improve their ability to comply with the revised IHR.

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Une traduction en français de ce résumé figure à la fin de l'article. Al final del artículo se facilita una traducción al español. الترجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة.

The revised International Health Regulations (IHR) represent a dramatic new approach to combating public health emergencies.[1] However, the success of the IHR may be impeded because of problems federal countries may experience in meeting their requirements.[2,3] Founded on a series of sanitary conventions dating back to the mid 19th century, the recently revised IHR aim to guide the response of Member States to public health emergencies, with a particular focus on preventing the international spread of disease without unnecessary disruption of trade or travel. Recognition of the limitations of previous versions, as well as growing awareness of the increased threat of infectious diseases in an ever-more interconnected world, prompted an extensive revision process which began in 1995 and concluded with unanimous approval of the new agreement in May 2005.[4,5]

The IHR (2005) reflect a substantial change in approach to international health governance, with the protection of the international community from public health threats granted priority over national sovereignty in certain circumstances.[6] Some of the more dramatic examples of this shift in approach include: new requirements for countries to report on potential public health emergencies within 24 hours; WHO authority to use nongovernmental sources of information for surveillance purposes; and the ability of WHO to issue public health recommendations such as those regarding travel, with or without the consent of potentially affected States Parties.[1–3] A further major innovation in the new IHR is the detailed requirement for States Parties to develop multilevel capacities (referred to as core capacity requirements) to effectively manage public health threats (Table 1). The revised IHR impose on all WHO Member States the explicit obligation to develop, strengthen, and maintain the capacity to detect, report and respond to public health events.[7] When combined, the required capacities constitute a blueprint for a comprehensive, fully-integrated, public health emergency detection and response system.

The IHR outline "core capacity requirements for designated airports, ports and ground crossings". These requirements should not be problematic for most federal countries to implement since international points of entry normally fall under the jurisdiction of national governments. Potential compliance problems, however, can emerge with regard to those core capacities over which federal governments may not have explicit jurisdiction. For example, surveillance powers may fall to the regional (such as state, provincial or cantonal) level of government in many federal countries. Federal governments may not have the authority to implement local level surveillance or guarantee the transfer of epidemiological data from local to national levels

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Table 1. **Core capacities for surveillance and response**

Obligations of States Parties to IHR (2005)	Local level	Intermediate level	National level
Core capacities	• to detect unusual public health events • to report key epidemiological information to relevant intermediate and national authorities • to immediately implement primary control measures	• to evaluate and verify epidemiological data • to implement additional control measures as necessary • to report to national authorities	• to assess within 48 h all domestic "urgent events" by consolidating input from and disseminating information to relevant sectors of the administration • to report the results of assessments as required within 24 h to WHO through a national focal point (NFP) which must be accessible at all times for communications
Points of entry capacities	• to provide and maintain facilities and expertise to conduct inspection (of goods and conveyances) and interview, diagnosis and treatment (of travellers) at designated points of entry		
Cross-cutting capacities	• to conduct 24 h/7 day surveillance and inspection, reporting, notification, verification, response, and collaboration with domestic and international public health authorities • to develop and maintain trained specialized personnel and facilities for health data collection, laboratory investigation and operational/logistical support (including communication, transportation and supply chain), and detailed national public health emergency plans that specify multi-sectoral response teams • to implement the regulations and conduct of public health interventions "with full respect for the dignity, human rights, and fundamental freedoms of persons" (and as guided by the UN Charter and WHO Constitution) • to assess existing national capacities to comply with the terms of the IHR (2005) within 2 years (and to achieve full compliance within 5 years) of the entry into force of the agreement		
Capacity-building in low-resource countries	• for WHO and State Parties to assist in the development of public health capacities everywhere, including the provision of technical cooperation and logistical support, as well as the mobilization of financial resources to facilitate implementation of the IHR		

IHR, International Health Regulations; PHEIC, public health emergencies of international concern.

to meet IHR (2005) requirements. Compounding matters is the fact that voluntary compliance from the local level cannot be presumed due to resource limitations at this level or fear of economic consequences related to early reporting of potential emergencies.

The potential difficulty in reconciling federal systems of government with the IHR (2005) is illustrated by a request made by the United States of America for an article declaring that it would implement the regulations in a manner that is most consistent with its federal system of government.[8] The rejection of the USA's request suggests that other federal countries did not view their systems of government as an insurmountable obstacle to implementation of the IHR (2005).[9] To the contrary, the unanimous approval of the IHR (2005) by all members of the World Health Assembly, including its federal countries, is evidence of a global recognition of the importance of the agreement as well as of the general willingness of States Parties to take measures to overcome domestic obstacles to its implementation.

Implementation in federal countries

Addressing the domestic governance challenges created by an increasingly demanding global public health regime is not a simple task. While all countries share an interest in addressing global public health emergencies through the revised IHR, they differ in important ways that will have an impact on the viability of various strategies to implement the agreement. Every country has a unique governance system, as well as a legal framework (constitutional or otherwise) that places limitations on the design of policies and practices. Countries also have unique histories, including experiences with public health emergencies and acceptance of national government intervention. In some federal countries, India for example, it may be considered more acceptable for national governments to intervene in local issues, particularly if that intervention brings much needed resources to manage public health threats.

No one set of policy options will be appropriate for all federations. To determine the appropriate approach for federal countries, the following fundamental questions need to be answered: (1) To what extent can federal countries ensure compliance with the IHR within the context of a decentralized approach to public health? (2) If federal countries adopt more centralized approaches to public health, how should they manage the potential negative impacts of such reforms on their relationships with regional and local public health authorities? (3) In either case, how coercive are federal governments justified in being towards regional governments to ensure that the coordination of public health necessary for compliance with the IHR takes place?

Governance options

To effectively implement the IHR, federal governments will need to take steps to either centralize governance, or at the minimum, increase harmonization of public health policy and practice at the level of regional government. The latter will require creating a structure whereby regional governments are encouraged to develop the appropriate local public health

capacity and pass necessary public health legislation that will allow the country to meet IHR requirements. Federal governments have different instruments they can utilize to achieve these goals. These include direct legislation within the area of public health, legislation within a parallel area that covers the matters of interest, funding arrangements, the use of intergovernmental agreements, and the issuance of national guidelines. Each of these has advantages and disadvantages and it is important to identify the combination of instruments that can optimize the likelihood of successful compliance with the IHR while mitigating its potential harms (Box 1).

Box 1. **Key messages from symposium**

Participants in the symposium included senior public health experts from, but not officially representing, the following: Australia, Canada, China, France (China and France are examples of decentralized unitary countries), India, the Russia Federation, Senegal (as a general representative of regional governance in Africa), the United States of America and WHO. The views, opinions and conclusions expressed in this paper do not necessarily reflect those of WHO or participating countries.

Each of the countries involved had uniquely different experiences with implementing the International Health Regulations (IHR). Australia, Canada and the USA were confronted with the challenge that authority over several of the core capacity requirements was primarily located at the state or province level. Each of these countries has potential mechanisms by which these powers could be centralized, although such a process may be contrary to the history of federalism within that country and could be viewed as harmful to the integrity of the public health system.

The intention of these countries is to manage these issues through collaborative approaches such as harmonization of legislation, funding arrangements and memoranda of understanding. Brazil, India and the Russian Federation have systems in which necessary legislative authority exists at the federal level and regional governments are dependent on central governments for funding, which allows conditions to be attached to funding. These countries have more governance mechanisms by which to implement the IHR although public health capacity at the local or regional level remains a critical issue. The representative from Senegal identified the need for coordination of governance not just within each country but also with adjacent countries with which borders are often crossed in daily activities and from which diseases could spread.

Legislation

Among the options available to federal governments, the legislative approach is likely to be considered one of the most intrusive, or least respectful, of regional sovereignty. But it may also be one of the most effective mechanisms for the implementation of the IHR (2005). The ability of a national or federal government to exploit this option will in many cases depend on the allocation of powers in the constitution. If the federal government has clear constitutional jurisdiction, it could pass legislation imposing requirements on local or regional public health authorities. This legislation could provide for surveillance capacity development at the regional level, compulsory reporting of public health threats and allow for federal intervention in public health emergencies. The IHR (2005) decision instrument for identifying a public health emergency of international concern (PHEIC) could be adopted as a federal test for jurisdiction for the latter issue: if a public health emergency is found to be of international concern according to the algorithm contained in the instrument, then the federal government would automatically have jurisdiction over the matter. India, for example, has proposed new legislation that explicitly provides the federal government with authority over a WHO-declared PHEIC.

The constitutions of many countries, however, are silent on the allocation of public health powers between levels of government, with the result in most cases being concurrent jurisdictional authority for activities related to the IHR. On the other hand, parallel constitutional powers often provide mechanisms through which federal governments can gain the needed legislative authority. In Canada, for example, the criminal law power has been used by the federal government to regulate in public health.[10] In the USA, the federal government's tax and spending powers and its ability to regulate interstate commerce provide the opportunity to extend its influence in many public health matters.[11] The constitutions of some federal countries also contain variations of a "supremacy clause" whereby conflicts between regional and federal legislation (including treaty law) are resolved in favour of federal law.[12]

The use of these alternative approaches must be considered with particular caution. The expansion of federal authority into an area not otherwise constitutionally enumerated runs the risk of being viewed as a power grab, and could damage essential collaborative intergovernmental relationships. Moreover, unilateral assertions of federal authority, whatever the legal grounds, are unlikely to be effective in the absence of regional cooperation, and could, in the worst case, generate animosity sufficient to seriously impair responses during a public health emergency.[13] Thus such measures and approaches should only be considered once other less intrusive alternatives have failed, and only when a federal government judges that its lack of legislative authority poses a significant threat to its citizens or to the international community.

An intriguing and controversial approach to establishing a legislative basis for federal authority to intervene during public health emergencies is through the use of security powers. This is an option that has been considered by the United States and Australia, which has recently enacted legislation that links public health surveillance with national security.[14,15]

The securitization of public health has implications that need to be carefully considered.[16–18] A primary advantage is that it could provide the federal government with the necessary powers to take aggressive action early in a public health emergency. Including public health as an essential component of security also raises the profile and visibility of the former, which may in turn result in increased resources for population health. However, securitization is in direct opposition to the fundamental ethos of public health based on collaboration. It also necessarily makes public health concerns secondary to security concerns, and so public health emergencies could ultimately fall under the authority of security officials as opposed to public health officials.

Importantly, the consideration of any legislative approach must also respect other aspects of a nation's constitution, notably human rights provisions. Respect for human rights is also explicitly made

obligatory under the IHR (2005), which requires that domestic implementation be guided by the UN Charter, the WHO Constitution, and "with full respect for the dignity, human rights, and fundamental freedoms of persons".[19]

Funding power

Ultimately legislative authority at the federal level is meaningless without necessary capacity at the regional or local levels. Moreover, strengthening public health capacity to meet the requirements of the IHR (2005) will require significant resource commitments in most countries. One way to achieve enhanced capacity, while ensuring that local and regional authorities transfer relevant public health information to national governments, is through conditional funding arrangements. These would most likely involve agreements between federal and local or regional governments to share the costs of developing surveillance infrastructure in exchange for guaranteed transfer of epidemiological information to the national level. From a political perspective, such an arrangement may be viewed as less intrusive than a legislative approach. It also has the potential to achieve the same or better results on the ground, particularly when there is a large financial asymmetry between national and regional governments. However, some regional governments may still regard the attachment of conditions to federal dollars as coercive and could potentially restrict the optimal use of these dollars at the local level. This is particularly true in developing countries dealing with the burden of multiple public health threats, such as HIV, tuberculosis and malaria, which they are already insufficiently resourced to manage.

Intergovernmental agreements

Another less intrusive option than legislation is the creation of formal negotiated agreements between different levels of governments. These would be mutually agreed upon and would therefore respect jurisdictional boundaries. Memoranda of Understanding (MOU) could be particularly effective for issues such as data transfer and could be used to formalize funding arrangements. They might also establish the level of authority the federal government would have in the event of a regional public health emergency of possible national or international concern. Canadian federal and provincial authorities have been considering the use of an MOU related to data transfer, based on the PHEIC algorithm proposed in the decision-making instrument in Annex 2 of the IHR (2005). Australia has developed an intergovernmental agreement to outline the mechanism by which an emergency will be declared.[20] However, in the absence of additional funding arrangements or compensation plans, such agreements could be difficult to enforce. Tensions are likely to arise when regional governments are faced with the actual decision to report a public health emergency which could risk damage to the local economy. One approach to diffusing such tensions would be to pursue intergovernmental agreements for the creation of independent bodies to oversee public health activities (during emergencies and otherwise) that could act at arms' length of government. The degree of autonomy of such organizations will be dependent upon the legislative framework within which they must operate as well as the source of their funding.

National guidelines

Another minimally intrusive approach is the creation of national guidelines with regard, for example, to the standardization of data collection, storage and reporting. Regional and national data standardization remains a major obstacle in most countries, where there is a need to develop compatible, if not fully-integrated, information technology platforms for the collection, analysis and communication of information during a public health emergency. Guidelines, while not binding, could be used to encourage such harmonization and could lead to increased cooperation from local governments if they are invited to participate in the process of guideline formulation. Another advantage of guidelines, as compared to legislation, is that they can be rapidly modified to remain current with changing technologies and evolving public health science and practice. Guidelines are most likely to be effective if used in combination with another strategy, in particular conditional funding arrangements. For example, the Pandemic and All-Hazards Preparedness Act in the USA provides an example of how federal funding to states can be made contingent on meeting federal standards.[21]

Conclusion

We have presented several governance strategies that federal countries could consider when determining how to comply with the revised IHR (summary in Table 2). Our recommendations are intended for federal governments but may also be useful for decentralized countries with unitary systems of government. While in these countries the central government always has a legislative option, the importance of maintaining effective collaborative relationships should encourage the consideration of other approaches.

There is no single solution to the challenges faced by federal States Parties to the revised IHR. In all likelihood, a combination of strategies based on specific circumstances will have to be developed for each country. However, a couple of over-arching themes emerged from the proceedings of our workshop. First, we expect the greatest challenges to occur in meeting the surveillance, reporting and response requirements of the IHR. The revised IHR require that a single body within every country has the responsibility to communicate to WHO about potential PHEIC. Assuming this will be a federal agency, the most effective mechanism by which to ensure it has the required information would be to incorporate the Annex 2 decision instrument either into legislation or an MOU between federal and regional governments. If and when a potential PHEIC is detected, the federal agency must possess sufficient authority to assess and acquire all available pertinent information so as to meet the IHR reporting requirements. Second, ongoing challenges such as surveillance at the local level are likely to be handled better through more collaborative approaches that combine conditional funding to develop capacity with intergovernmental agreements to formalize relationships and responsibilities. National guidelines could be used for matters in which standardization of practices is sought.

Whatever the combination of strategies used, their ultimate success will depend crucially on the development of appropriate public health capacity at all levels of government, as well as effective working relationships between the various stakeholders. Furthermore, devolution of public health activities or powers to nongovernmental entities, for example in the form of privatization, can make agreements between govern-

Table 2. **Summary of governance strategies**

Governance strategies	Advantages	Disadvantages	Potential area of use
Legislation	• enforceable • clear designation of roles and responsibilities • clear lines of accountability	• dependent on existence of appropriate constitutional authority • may damage relations with other levels of government • inflexible	• authority to oversee and guide response to a PHEIC • mechanism to ensure transfer of epidemiological data to national level
Funding arrangements	• enforceable • links capacity development to governance strategy • respects constitutional boundaries	• may be changed unilaterally by national government • may be viewed as coercive • creates some ambiguity as to accountability	• surveillance capacity development in combination with meeting IHR reporting requirements
Agreements	• respects constitutional boundaries	• limits to enforceability	• mechanism to ensure transfer of epidemiological data to national level
Guidelines	• respects constitutional boundaries • flexible	• least enforceable	• standardization of data

IHR, International Health Regulations; PHEIC, public health emergencies of international concern.

ments meaningless and threatens to undermine compliance with the IHR by limiting the ability of countries to gather and aggregate public health information.[22,23] Any implementation strategy that does not take these factors into serious consideration is likely to be ineffective in promoting compliance with the IHR (2005). ■

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Résumé

Stratégies de mise en œuvre du nouveau règlement sanitaire international dans les Etats fédéraux

Le Règlement sanitaire international (RSI), principal instrument juridique guidant la prise en charge internationale des urgences de santé publique, a récemment fait l'objet d'un processus de révision approfondi. Le règlement révisé, appelé RSI (2005), a été approuvé à l'unanimité en mai 2005 par tous les Etats Membres de l'Assemblée mondiale de la Santé (WHA), puis est entré en vigueur le 15 juin 2007. Le RSI (2005) reflète la modernisation de l'approche de la santé publique par la communauté internationale et la reconnaissance de l'importance d'une stratégie internationale efficace pour faire face aux situations d'urgence qui menacent la sécurité sanitaire mondiale.

Le succès du RSI, en tant que nouvelle approche pour combattre ces menaces, sera conditionné en dernier ressort par la capacité des pays à s'acquitter des obligations auxquelles ils se sont soumis en approuvant la nouvelle stratégie internationale. Néanmoins, respecter ces obligations risque d'être particulièrement difficile pour les pays décentralisés, notamment ceux dotés d'un système fédéral de gouvernement. Si le RSI (2005) est le fruit d'un accord entre gouvernements nationaux, il couvre une grande variété de questions, dont certaines ne relèvent pas totalement du gouvernement national dans nombre de fédérations. Cette tension entre la séparation des pouvoirs au sein des systèmes de gouvernement fédéraux et les exigences d'un régime de gouvernance sanitaire mondiale en évolution pourrait saper les efforts au niveau national pour respecter le règlement et finalement remettre en cause le succès de cette gouvernance.

Nous avons accueilli un atelier chargé d'examiner comment les Etats fédéraux pourraient répondre à certaines de difficultés qu'ils risquent de rencontrer dans l'application du RSI (2005). Nous présentons dans cet article une série de recommandations, formulées à partir des actes de l'atelier, sur les stratégies que pourraient suivre ces pays pour améliorer leur capacité à respecter le RSI révisé.

Resumen

Estrategias para aplicar el nuevo Reglamento Sanitario Internacional en los países federales

El Reglamento Sanitario Internacional (RSI), que constituye el principal instrumento jurídico disponible para dirigir la gestión internacional de las emergencias de salud pública, ha sido objeto recientemente de un extenso proceso de revisión. El Reglamento revisado, conocido como RSI (2005), fue aprobado por unanimidad en mayo de 2005 por todos los Estados Miembros de la Asamblea Mundial de la Salud y entró en vigor el 15 de junio de 2007. El RSI (2005) refleja el enfoque más moderno que aplica a la salud pública la comunidad internacional, así como el reconocimiento de la importancia que reviste el establecimiento de una estrategia internacional eficaz para controlar las emergencias que amenazan la seguridad sanitaria mundial.

El éxito del RSI como una nueva perspectiva para combatir esas amenazas dependerá en último término de la capacidad de los países para cumplir las obligaciones que asumieron al aprobar la nueva estrategia internacional. Sin embargo, ello puede representar una tarea especialmente ardua para los países descentralizados, sobre todo para los que cuentan con sistemas federales de gobierno. Aunque es fruto de un acuerdo entre gobiernos nacionales, el RSI (2005) abarca una amplia gama de asuntos que pueden quedar fuera de la jurisdicción constitucional del gobierno nacional en muchas federaciones. Ese conflicto entre la separación de poderes que se da en los sistemas federales de gobierno y las exigencias de las nuevas formas de gobernanza de la salud pública mundial puede minar los esfuerzos nacionales encaminados a garantizar el cumplimiento de las medidas propuestas y a la larga podría poner en peligro el éxito de esas medidas.

Organizamos un taller para estudiar de qué manera podrían los países federales afrontar algunos de los desafíos que puede plantear la aplicación del RSI (2005). Presentamos aquí una serie de recomendaciones, sintetizadas a partir de lo discutido en el taller, sobre las estrategias que podrían adoptar esos países a fin de mejorar su capacidad para cumplir lo dispuesto en el RSI revisado.

ملخص

استـراتيجيات تنفيذ اللوائح الصحية الدولية في البلدان الفيدرالية

تعد اللوائح الصحية الدولية الأداة القانونية الأساسية التي تسترشد بها الإدارة الدولية للطوارئ التي تتهدد الصحة العمومية، وقد خضعت مؤخراً هذه اللوائح إلى عملية مراجعة شاملة، وأصبحت اللوائح المنقحة تعرف باللوائح الصحية الدولية (2005)، وقد حازت على موافقة جميع الدول الأعضاء في جمعية الصحة العالمية بدون استثناء في شهر أيار/مايو 2005، ودخلت حيز التنفيذ في 15 حزيران/يونيو من عام 2007، وهي تعكس السمات العصرية للأسلوب الذي ينتهجه المجتمع الدولي في الصحة العمومية مع اعتـرافه بأهمية توطيد استـراتيجية دولية فعالة لإدارة الطوارئ التي تهدد الأمن الصحي على الصعيد العالمي.

إن نجاح اللوائح الصحية الدولية كأسلوب جديد في مواجهة مثل هذه التهديدات هو أمر ستحدده مقدرة البلدان على الوفاء بالالتزامات التي قطعتها على نفسها لدى موافقتها على الاستـراتيجية الدولية الجديدة، إلا أن تنفيذ ذلك سيكون بحد ذاته تحدياً للبلدان البعيدة عن المركزية، ولاسيما البلدان ذات النُظُم الحكومية الفيدرالية. فرغم أن اللوائح الصحية الدولية 2005 هي نتاج الاتفاق بين الحكومات الوطنية، فإنها تغطي طيفاً واسعاً من القضايا، بعضها قد لا يندرج تحت التشريعات الدستورية للحكومات الوطنية ضمن الكثير من الفيدراليات. وقد يؤدي هذا التوتر بين انفصال القوى ضمن النُظُم الفيدرالية للحكومة وما تتطلبه النُظُم المستجدة للحكامة في الصحة العمومية العالمية إلى إضعاف الجهود الوطنية الرامية الى الامتثال للوائح الصحية الدولية وقد تهدد بالتالي نجاح نظامها.

وقد استضاف القائمون على هذه الدراسة حلقة عملية لدراسة كيف يمكن للبلدان الفيدرالية مواجهة بعض التحديات التي قد تواجهها في تنفيذ اللوائح الصحية الدولية 2005، ويعرضون في هذه المقالة سلسلة من التوصيات التي جمعت من وقائع الحلقة العملية حول الاستـراتيجيات التي قد تتبعها هذه البلدان لتحسين قدرتها على الامتثال للوائح الصحية الدولية المنقّحة.

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