ICIUM 2011 Topic Summaries

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Medicines Access

Theme 1 - Policy Strategies to Improve Access to Medicines

Introduction

Policies and strategies to improve access to medicines need to be considered at different system levels:

1. At global level, ICIUM 2011 conference clearly acknowledged the role of the private pharmaceutical sector, including generic manufacturers (see Theme 17). These stakeholders are important players and willing to be partners but their interests must be balanced with those of other stakeholders and there is a need to manage dynamic tensions that exist (541, 1239, 1242, 1291). One important global strategy for better access to medicines could be various pooling arrangements: pooling of ideas, innovations, data, funds and resources (972, 1011). Unfortunately, traditional donors do not pay sufficient attention to these opportunities.
2. At national level, important issues were raised such as the need to consider the pharmaceutical sector in the wider context of national health systems and social, cultural, and political environments (1309). In that regard, maintaining the equity perspective on access to medicines is very important, as lack of social health protection, ethnic origin, gender and socio-economic status impact access to medicines (794).
3. At provider level, it is important to maintain past efforts in improving medicines use, although proven effective interventions in that area are sometimes difficult to implement in resource poor settings (e.g., Drug Therapeutic Committees) (690). Task shifting and contribution of the informal sector should also be considered as important elements impacting medicines use (1071).
4. At community level, health seeking behavior and communities preferences are important elements of access to medicines (210).

Policy and Program Recommendations

1. Multi-layer governance is needed if we aim at addressing access to medicines issues effectively: at international, national and community levels. As a consequence, a structured approach to the policy process which includes multi-stakeholder participation should be envisaged. This includes the private sector both at international and national levels (1309).
2. Pooling mechanisms may be useful in certain conditions. Involvement of LMIC expertise and abilities is essential in establishing pooling arrangements (972, 1011).

3. Countries should place access to medicines and medicines use much higher on the political agenda. Several approaches were suggested such as establishing an independent inter-ministerial body that would monitor the situation and manage inappropriate incentives or a special unit reporting to the Minister of Health on medicines use (1058, 1093). More generally, there is a strong support for a better and higher level management of the pharmaceutical sector.

4. Public health policies in low- and middle-income countries need to pay further attention to access to medicines for chronic conditions (Improving medicines access and use for chronic conditions (system, provider, and patient level).

5. Policies for access to medicines need to look over and beyond financial access, and pay adequate attention to social and cultural issues, geographical access, general safety etc. They need to be designed taking in consideration patients preferences and communities health seeking behavior (794).

Key Research Recommendations

Further research is needed that focuses on the following recommendations:

1. Validate data collection and analytical methods for analyzing medicines situation (e.g., WHO Indicators), perform benchmarking and country comparisons, as these data are used for governance and decision making at all levels of the system (337, 1058, 1093).

2. Future studies on access to medicines should consider social determinants, health seeking behavior and other factors to inform policies (265, 318, 760, 762).

3. Combine household and facility surveys to monitor the effects of pharmaceutical policy change (1253).

4. Investigate the performance of the private sector with regard access to medicines. What are the main determinants of success and failures (270, 541, 1058)?

5. Identify bottlenecks in pharmaceutical R&D, followed by research on optimal pooling approaches to address the bottlenecks (972, 1011).

Theme 2 - Technology Interventions to Improve Access to Medicines

Introduction

Technology interventions to improve access to medicines discussed at ICIUM 2011 can be categorized in three different groups:

1. Technologies that help improve medicines management (mainly supply and stock management. These include:
      - Innovations such as Standard Kits for use in primary health care settings (727), or Unit Dose Systems in multi-disciplinary or referral hospitals (563);
      - The use of mobile short messaging, internet and mapping services to prevent stock-outs (516, 722).
2. Technologies assisting providers and patients to improve medicines use through better adherence to treatment: these experiences have been piloted in several disease-specific interventions especially for patients under ARV treatment, and lead a great potential for patients living with chronic conditions such as diabetes (1259, 1260, 1261, 1262).
3. Technologies related to collection, analysis and dissemination of accurate information for decision-making: evidence exist that sharing information on medicines' price and quality improves access (883); similarly information exchange is crucial to combat counterfeit medicines, curb anti-microbial resistance (see Theme 13) and improve pharmacovigilance or procurement practices. Information and related technologies are needed to support transparency, which is a cornerstone of good governance for medicines (711). Access to accurate information is also essential to counteract the effects of unethical medicines promotion practices (1093).

A number of policy recommendations and research related to piloting, assessing and scaling up technology interventions for access to medicines can be formulated from posters and presentations at ICIUM 2011.

Policy and Program Recommendations

1. New technologies such as SMS, internet or mapping services can be effectively used to prevent stock-outs of a restricted number of essential medicines. These can also be effectively used to improve adherence to treatment for patients living with chronic conditions. They may also reveal effective in assisting anti-counterfeit interventions. Implementation of such technologies needs to be contextualized to resource-poor settings. They need to be integrated in and come in support to well-designed comprehensive interventions (516, 722).

2. Databases on medicines prices, quality and use should be developed, expanded and maintained. They should be placed in the public domain through knowledge portals allowing all stakeholders to access information (1058, 1093). Adequate technology and tools to collect data need to be in place at lower levels of the health system as well.

3. Routine data collection and information sharing should be complemented with specific large or small scale surveys (for example pricing survey, household survey, qualitative data collection), that offer a unique setting to access certain types of information (e.g., health seeking behavior, patients perceptions, etc.) (204, 794).

4. Strict regulation and enforcement of sanctions for unethical medicines promotion should be in place, including monitoring and reporting promotion practices of local marketing units and representatives, often disconnected from pharmaceutical companies' headquarters (1289).

Key Research Recommendations

Further research is needed that focuses on the following questions:

1. Can technologies such as SMS, internet and mapping services for preventing stock-outs or improving adherence be scaled-up nationwide in resource-poor settings? Are they cost-effective? How could they be applied to monitor adequate use, including antibiotic use and antimicrobial resistance? Can they be applied to the private sector and how (744, 876, 942, 990, 1058, 1093)?

2. How can several m-health technologies developed for different purposes (stock-outs, adherence, counterfeit) be integrated to avoid fragmentation of information and efforts (1053)?

3. How can patient electronic records be used to support medicines management (1083)?

4. How can standard household surveys, such as Demographic and Health Surveys, be improved to collect accurate medicines data (see Theme 21)?

5. How can robust data be collected from the private sector? Which methods could be used to avoid bias and data gaps (270)?

Medicines Policies

Theme 3 - Policies to Ensure Medicines Quality and Safety

Introduction

High standards of quality and safety of medicines must be ensured to obtain full benefits of medicines in patients. Policies and initiatives in this area were discussed during ICIUM2011 in plenary (policy track) and poster sessions. Issues related to medicines quality were discussed in approximately 15 accepted contributions (114, 195, 210, 219, 248, 427, 466, 511, 691, 730, 885, 1012, 1024, 1221, 1223). These and other contributions related to quality and safety of medicines showed that:

- Patients and healthcare professionals may use very different criteria in deciding their own perceptions about the quality of medicines.
- A set of core and complementary indicators has been developed for pharmacovigilance, based on structure, process and outcomes/impacts (1033).
- Well-known medication safety interventions can be effectively implemented in well-resourced hospital settings (627, 632, 812, 814, 870, 896, 1074).
- The WHO guidelines on donation are comprehensive. If they had been followed they would have prevented the burden of useless donations related to the tsunami in Sri Lanka (773).

Policy and Program Recommendations

1. Regulators need to identify the steps that will reinforce patients' and healthcare professionals' acceptance of the quality of generic medicines. This is especially important in the light of the findings that perceptions about the quality do not always match actual quality data.
2. Each country needs to do a baseline and periodic assessment of pharmacovigilance performance using the new set of indicators. This will provide insight in the progress made and highlight areas where improvement is needed.
3. Best practices in relation to adverse drug reactions (ADR) and medication error reporting need documentation and dissemination. Joint learning should be supported.
4. Ministries of Health should enforce the national policy on medicines donations based on the WHO medicines donation guidelines. The donor and recipient country should strictly enforce adherence to the guidelines, and not receive any unexpected medicines from donations. There is a mutual accountability and responsibility between donor and recipient country.

Key Research Recommendations

1. Research is needed to establish the feasibility of the proposed pharmacovigilance indicators. In addition, the targets for these proposed indicators should be determined. Another important question that needs to be answered is to which extent these indicators differentiate good from bad performance.

2. External accreditation may effectively improve the implementation of medication safety interventions. However, evidence is lacking whether this is truly the case (in different settings) and further research is therefore warranted.

Theme 4 - Policies to Facilitate Appropriate Use of Medicines Including Policies Affecting Medicines Promotion

Introduction

Within the ICIUM$_{2011}$ policy track, special attention was paid to policies that facilitate appropriate use of medicines, including policies and initiatives around conflict of interest and medicines promotion at different levels. Approximately 10 presentations and posters accepted for ICIUM2011 evaluated different aspects related to medicines promotion (146, 411, 510, 593, 599, 924, 1077, 1101). In addition, about 15 accepted contributions focused on generic policies and use of generics (114, 164, 271, 279, 359, 360, 427, 490, 691, 716, 885, 910, 998). Presentation and discussion of these and other contributions related to policies to facilitate appropriate use have led to the following observations:

- Regarding medicines promotion, targeted interventions to educate and empower the community as well as all health care workers can be successful at least in the short term and on a small scale (146, 510).
- The Access to Medicines Index is a potentially useful tool for monitoring at least a part of the industry, mainly the big innovators but also some key generics manufacturers (599). Country marketing practices frequently do not match stated company marketing policies at headquarter level.
- To get high penetration of generic medicines an integrated policy with strong political support by a "champion" is needed (910).
- There is limited evidence for palliative care policies (includes old medicines and off label use). A multifaceted systematic and integrated approach can integrate advocacy strategies in palliative care with the national medicines policy (1178).
- Health litigation is an unintended effect of "right to health" clauses in the constitution, which may have positive or detrimental effects on the pharmaceutical system and practice of rational use of medicines, depending on country context (555, 677, 679, 888, 891).

Policy and Program Recommendations

1. Involve payers, patients and health authorities at all levels in implementation of essential medicines programs including selection.
2. Countries need to have strong, practical and implementable policies to regulate all aspects of promotion. All prescribers including prescribing nurses, dispensers, and the community at large need to be targeted in educational interventions on promotional activities.

3. Regarding medicines promotion, there needs to be increased political will for change with transparency and collaboration among all stakeholders. Greater transparency needs to be shown by the industry about their promotional activities and ethical standards.
4. Strengthen the empowerment of the community and involvement of civil society. These groups need to be able to report on promotional activities and especially the breaching of codes at the end user level. Education on promotional activities and advertising should be introduced to *all* health workers in their various training programs at the earliest possible stages.
5. Peers make good trainers. Trainers should be taken to the workforce, not the workforce to the trainers.

Key Research Recommendations

1. The presentation on palliative care policies raises the question whether essential medicines criteria are appropriate for specific therapeutic areas such as but not limited to palliative care.
2. Research is needed to assess how the effectiveness of essential medicines lists can be maximized, including 1) raising public awareness 2) linking to payments, incentives, reimbursement 3) involving stakeholders, insurers, payers, 4) linking to standard treatment guidelines, 5) the place of traditional medicines, and 6) the processes of selection (experience or evidence) and implementation practices.
3. The best mechanisms for increasing generic prescribing, including 1) the effectiveness of mandatory or voluntary prescription orders, 2) the impact of the hospital, community interface, and 3) consumer awareness should be established.
4. A key question that needs further analysis is how the wording of right to health in a national constitution affects the amount of related litigation within the country.
5. More studies on promotional activities need to be done and data collected and disseminated in low and middle income countries as most of the research on medicines promotion has involved more developed countries to date. Evaluation of the outcomes (e.g. medicines prescribing or consumption of pharmaceutical promotional activities for health workers and patients is needed. What are the long term effects and sustainability of educational interventions in the community and also on health workers, not only focusing on knowledge and skills but also on behavior and health outcomes?

Theme 5 – Policies to Facilitate Good Governance, Transparency and Accountability in the Pharmaceutical Sector

Introduction

Many contributions within the ICIUM$_{2011}$ policy track dealt with aspects related to transparency and accountability in the pharmaceutical sector. Many accepted presentations and posters focused explicitly on good governance of medicines (see Theme 19; 193, 711, 751, 934, 955, 1040, 1064, 1154, 1161, 1189, 1193). All of these contributions and subsequent discussions led to the following observations:

- We need explicit policies on which implementation plans can be based. Data collection, analysis and effective presentation of results are essential to gain political support and induce change; prior, during and post interventions. Robust data collection and analysis are required and new technologies can facilitate data collection. Multidimensional approaches are required. Repetition and reinforcement are necessary for sustainability. Variations in performance and understanding across regions and settings need to be assessed.

- An integrated pharmaceutical management reporting system with mandatory reporting and public feedback helps to improve performance (1202). Recognition and positive incentives linked to measured performance facilitate participation and positive behavioral changes (731).

- An important component of policies to improve good governance for medicines has to do with transparency and accountability; making standard documents for good governance publicly available will give greater confidence in the system, enable policy makers to understand and to strengthen the gaps in their pharmaceutical systems, and empower individuals to initiate change at different levels and across various functions of the public pharmaceutical sector.

- In some countries, the price of medicines in the public sector is sometimes even higher than the private sector; corruption was reported to be the main driver for high medicine prices (193). Important factors affecting corruption include:
  o at individual level, professional ethics and personal values influencing prescriber behaviors and their response to corruption;
  o at systemic level, level of transparency, accountability, and legislation enforcement

Policy and program recommendations

1. Managing conflicts of interest in the pharmaceutical supply chain may help decrease corruption. A high level of commitment and enthusiasm and the use of a multidisciplinary

approach are crucial to the implementation and sustainability of good governance. At the country level, key documents related to good governance in the pharmaceutical sector should be disclosed for public access, to provide information about medicines regulation, inspection, selection, procurement, and registration.

2. All committees within the pharmaceutical sector need to make key documents publicly available, in particular documents addressing the management of conflicts of interest, criteria for member selection, standard operating procedures, and meeting minutes reporting actual decisions.

3. National medicines regulatory authorities need to be strengthened and supported, partly through harmonization and co-operation efforts.

4. Standards for medication management need to be established in overall healthcare quality improvement systems. Reward and recognition of good performance needs to be built into management and supervision systems.

5. Interventions proven to be effective should be institutionalized, monitored through ongoing data collection, and published to raise awareness of successes.

6. A *structured* multi stakeholder, multidisciplinary approach to the policy process ensures ownership by all partners. Objective monitoring of the impact and outcome of policy measures should be built into policy implementation from the outset, especially in the public sector. A special focus should be on monitoring changes over time through longitudinal data analysis. In large and/or decentralized countries, discrepancies between national and state or regional policies should be taken into account when considering the effects of interventions.

7. Issues about medicines access and use should be approached through a holistic health systems framework.

Key research recommendations

1. Frameworks for research in medicines policy should be developed and shared.

2. The impacts of disclosing documents related to issues such as conflict of interests and ethical criteria in the pharmaceutical sector should be evaluated.

3. Further research is needed to assess the challenges faced by countries in measuring progress towards transparency and good governance.

4. Further research using appropriate methods is needed to establish the cost consequences and benefits of effective interventions.

Economics

Theme 6 - Medicines Pricing Strategies and Their Effects

Introduction

Medicine prices remain a significant barrier in access to quality medicines for the poor, especially in low- and middle-income countries (LMICs). Out-of-pocket payments are a regressive medicine financing mechanism that deters utilization (307, 957, 1165). Improving medicines affordability remains a key priority for policy makers, targeting key leverage points in the pharmaceutical system and utilizing various policy alternatives at their disposal (397).

1. Efficient public sector procurement (243, 356, 413, 1173) and delivery systems are an important strategy for making medicines accessible to populations in the public sector.

2. Exchange of information about medicines prices can improve procurement decisions. The World Health Organization Western Pacific Region (243, 883) has demonstrated that web-based platforms for price information exchange can be an effective tool at regional level.

3. Quality reporting databases (1012, 1109) have positive impacts on medicine prices. However, external reference pricing (747) and equity pricing (1209) may be inferior to free market competition as mechanisms to address medicines prices. (Session 1C: 747, 883, 957, 1109, 1209)

4. There is limited evidence on the effectiveness of regulating supply chain mark-ups in LMICs and unexpected medicine supply problems might occur using these mechanisms (287). Taxes and tariffs on medicines remain a contentious issue and removing them could reduce medicine prices, but the macro-economic impact is unclear (498).

5. The speed of the shift in national pharmaceutical markets away from originator brand products and the degree of reliance on branded versus unbranded generics depend on many factors and differ significantly among regions (716).

Policy and Program Recommendations

Based on available evidence about policy interventions to reduce medicine prices and improve affordability, governments, international organizations, and other stakeholders should:

6. More clearly define which "price" is the focus in policy interventions , e.g. procurement price vs. end-user price, applicable incoterm, tax-inclusive vs. tax-exclusive etc. (Session 1C: 747, 883, 957, 1109, 1209)

7. Establish and maintain publicly accessible procurement price databases (such as the WPRO, WHO-HAI, or Unitaid price information databases) in each region as they provide a

useful resource for procurement agencies about prices of pharmaceuticals. (Session 2C: 287, 498, 716, 847, 1173) Establish national requirements for greater transparency about price information, including public disclosure of government procurement prices, supply chain mark-ups, and price components, including underlying R&D costs. (Session 1C: 747, 883, 957, 1109, 1209)

1. Critically evaluate the impact of pricing interventions and policies by integrating an explicit plan for monitoring and evaluation into every policy change. (Session 2C: 287, 498, 716, 847, 1173) The evaluations should use strong research designs that compare pre- and post-policy outcomes and include relevant comparator groups. Such evaluations will require consistent data collection over time on key outcome measures such as patient access/use and end-user price.

2. Adopt multi-faceted policy approaches which are more likely to be effective than single policies implemented in isolation, and can have unintended consequences. (Session 2C: 287, 498, 716, 847, 1173) When designing pricing policies, governments should consider policy impacts in the context of the entire health care system and cross-sectoral integration of policies.

3. Establish consumer- and provider-oriented communication programs to address general perceptions related to the low quality of generics. A prerequisite is that the regulatory authority can ensure that only high quality generics are registered. Available information about the quality of generics on the market should be publicly disclosed. (Sessions 4C: 114, 343, 718, 878, 947; 5C: 173, 285, 307, 1223)

Key Research Recommendations

There is a scarcity of well-designed longitudinal research in LMICs on the impacts of government policies to reduce medicine prices, development of alternative supply channels, novel financing mechanisms, or economic incentives on the quality of prescribing and dispensing. Some key research questions are:

1. What is the link between medicine price reduction, affordability, access, utilization, and patient outcomes (quality of life, mortality, and morbidity)?

2. What is the impact of greater transparency about the underlying components of medicine prices (such as manufacturing cost, recovering R&D costs, ongoing marketing costs, and supply chain mark-ups)?

3. What are the underlying causes (or policies) that influence variations in medicine prices and generic penetration between regions, countries, and sectors within a country?

Theme 7 - Affordability of Medicines By Households

Introduction

Poor access to health care and medicines remains a major barrier to health improvement in low- and middle-income countries (LMICs). Access is a complex phenomenon determined by many interrelated factors (1242, 1243, 1309), which complicates policy decisions. Many policies that aim to expand access to medicines can have unintended consequences.

8. User fees are often used as a method to finance the health system through out-of-pocket payments in LMICs. In Zambia (1168), removal of user fees led to an increase in health care utilization and quality of care remained largely positive. No data on health outcomes were reported. In a randomized controlled trial in Ghana (307), there was a significant increase in utilization of health care services in the group without user fees, but health outcomes did not differ, suggesting that complementary policies to improve service quality are needed.

9. Household surveys in 5 countries (1223) conducted using a standard WHO methodology provided valuable information about consumer knowledge and perceptions concerning medicine quality, pricing, and effectiveness to guide policy interventions. Perceptions that low cost medicine (generics) equals low quality have a significant impact on patient behaviour, access, and affordability (210).

10. High financial burden due to the cost of medicines (276) and other non-pharmaceutical costs of obtaining care (1229) places families at risk of poor clinical and economic outcomes. A study using data from the WHO/HAI Project on Medicine Prices in 16 countries (173) showed that buying originator brand antibiotics could potentially impoverish up to 23% of the population compared to only 12% if lowest cost generics are available. Data from 36 countries (285) illustrated the negative effects on access due to low public sector availability and high private sector medicine prices.

Policy and Program Recommendations

To improve household access to and affordability of medicines, governments, international organizations, and other stakeholders should:

4. Use *evidence about price and affordability for advocacy* to increase constitutional guarantees of the right to medicines (555), to raise awareness and lobby for additional

government funding for health and medicines (944, 975) and removal of user fees and other cost barriers (307, 1168).

5. Take a more active role in *communicating about quality assurance* activities, including establishing regional networks, public transparency about quality testing results, and countering false industry messages about product quality (219, 248, 1221).

6. Establish *regional, multi-country cooperation on medicines registration*, to gain efficiencies, encourage manufacturers of inexpensive medicines to apply for registration of their products in regional markets, and improve competition (535, 557).

7. Extend the *scope of the WHO-HAI Project on Medicine Prices* (173, 204, 285, 357, 421, 453, 478, 706, 775, 1145) to include: more focus on monitoring (933, 1148), additional measures of affordability (e.g., impoverishment, impact of prices by income quartile) and price (e.g., most sold at outlet, leading branded generic), and an extended series of policy reviews (236, 287, 490, 498, 747, 847, 904, 1086).

8. Expand *consumer involvement* in work on affordability in order to understand community needs and perspectives, and identify the best ways to communicate with the public (427, 553, 602, 604, 1199, 1206).

Key Research Recommendations

Using appropriate study designs, researchers should focus on:

4. More *qualitative research on affordability* (e.g, public perceptions, professional response to incentives, political and economic barriers to reform) to explain quantitative findings and generate new ideas for approaching access problems (300, 640, 1143).

5. Evaluating the *impact of reducing financial barriers* (such as medicine price reduction or expanded insurance coverage) on medicines affordability, utilization, adherence, clinical and quality of life outcomes, household financial burden, and non-health expenditures (307, 1168, 1242,1243,1309).

6. Integrating *longitudinal data on medicines utilization, availability, and price* in different outlets into routine policy monitoring (see Theme 20).

7. Expanding the number and frequency of *household medicines surveys (386, 527, 851, 970, 1035, 1208, 1214, 1223, Methods 4)* – and innovative uses for these data (e.g., evaluating policy effects, linking to medicine price or quality of care surveys).

Medicines and Non-Communicable Diseases

Theme 8 - Policies to Improve Medicines Access and Use for Chronic Diseases

Introduction

Low- and middle-income countries (LMICs) face an escalating prevalence of non-communicable diseases (NCDs) associated with increasing population longevity. Many LMICs now face the double burden of acute and chronic diseases, while little global attention and resources are given to chronic conditions other than HIV/AIDS (300). ICIUM presentations raised the following key issues:

1. The policy framework for managing NCDs in LMICs requires innovation, financing, and an emphasis on communities and patients (875, 1310). From a national health system perspective, a collaborative approach is essential to address equity and sustainability issues and to provide the integrated response necessary to chronic care (152, 825, 954, 1178).

2. Medicines availability and affordability are important barriers to the treatment of NCDs (152, 285, 775, 941). A secondary analysis of pricing surveys from several LMICs showed that mean availability of generics to treat chronic conditions was lower that the main availability of generics to treat acute illness, both in the public sector (36.0% versus 53.5%) and in the private sector (54.7% versus 66.2%), suggesting that supply systems give priority to medicines for acute illnesses over medicines for chronic diseases (204). In addition, medicines to treat chronic conditions are often not affordable (357), and household data indicate that only 31% and 45% patients with hypertension and diabetes respectively take their medicines as indicated (1208).

3. Implementation of Standard Treatment Guidelines (STG) may improve patient outcomes (705). However, adherence to STGs is often very low because of lack of coordination between procurement, supply, and prescribing (508); prescribers dissatisfaction with STGs (740); lack of provider and patient education leading to incorrect diagnosis or treatment of symptoms without considering associated health conditions; and lack of pharmacotherapy monitoring and feedback to prescribers (128, 804, 1134). Multiple barriers still exist in LMICs to monitor prescribing routinely from electronic medical records (543, 667).

4. So far, little research has focused on the private sector even though it represents the largest source of medicines for NCDs. Limited evidence suggests that private pharmacies can contribute to strengthening care for chronic conditions (371, 721).

5. The higher prevalence of co-morbidities in elderly is associated with acute exacerbations of NCDs and frequent use of potentially inappropriate medications (812, 1190).

Policy and Program Recommendations

1. Global and national programs and policies to improve the care of chronic diseases in LMICs should actively involve communities, families, and individuals. Community health care workers should be incentivized to play a role in patient education.

2. A key objective for LMIC policymakers should be to increase affordability and availability of both diagnostic tools and medicines for NCDs. Removing taxes and limiting mark-ups could be one step towards improving affordability for households and individuals. Routine monitoring of affordability and availability should be implemented to ensure accountability. Consumers should be informed about the cost of medicines to the health system, to individual patients, and to households.

3. The development of STGs for NCDs should involve affected patients. STGs need to be adapted to local cultures and organizational contexts and they should be updated regularly. Adherence to STGs should be monitored routinely. STGs implementation needs to be evaluated both in terms of clinical outcomes and process outcomes.

4. Education curricula and continuous professional training of all health care providers should include STGs. Health professionals should receive regular feedback on their adherence to STGs (235, 448, 468).

5. Policies to improve access to medicines for NCDs should involve the private sector since it represents the main access point for medicines in many LMICs.

Key Research Recommendations

Methods to evaluate chronic care delivery models should include qualitative methods such as anthropology. The results of research should be used to inform policymakers, health care providers, and the public, about the importance of medicines to treat NCDs and about their cost. Further research is needed to:

1. Identify effective and financially sustainable models of chronic care delivery that can be scaled up effectively.

2. Investigate delivery of both pharmacotherapy and patient education.

3. Develop and implement low-cost mechanisms to routinely monitor availability and affordability of medicines for NCDs.

4. Assess the costs and outcomes of disseminating STGs for NCDs, identify effective incentives to improve adherence to STGs, develop and implement routine monitoring of adherence to STGs.

Medicines and Child Health

Theme 9 - Improving Medicines Access and Use for Children

Introduction

The treatment of child illnesses remains suboptimal across the globe, and children in low-and middle-income countries (LMICs) lack access to medicines especially for non communicable diseases (338, 421, 524, 608, 771, 784). Different stakeholders (e.g., public and private sectors, civil society, non-governmental organizations) play important and complementary roles in addressing these issues; however, engaging the unregulated private sector to improve access to and use of medicines by children has been particularly challenging (434).

Encouraging results from new multifaceted strategies were presented at ICIUM, suggesting that some interventions targeting children are feasible and effective in low-resource settings such as strategies to improve the performance of:

o Traditional birth attendants (1218);
o Community health workers (746);
o Medicines retail outlets (Accredited Drug Dispensing Outlets - 132, 921, 1071);
o District hospitals (678);
o National immunization systems (433, 477, 1037).

Policy and Program recommendations

To improve access and use of children's medicines, the following recommendations are made:

1. Essential Medicine Lists (EMLs) should be harmonized with Standard Treatment Guidelines (STGs) that exist for children. EMLs should include pediatric formulations, and should be reviewed regularly to reflect current scientific evidence (499, 612, 647).

2. Continuous education to encourage appropriate use and availability of pediatric medicines/formulations is essential at all levels in the health systems (606, 851,1067, 1204). Education on medicine use for children should include new target groups such as school children (553, 659, 1054).

3. When designing and evaluating interventions targeting medicines for children, it is critical to adopt a "systems thinking" perspective that takes into account all related aspects of governance, financing, human resources, service delivery, as well as medicines/vaccines and information technologies (267, 615, 787, 835, 865, 1069).

4. In their efforts to improve the use of children medicines, countries should engage all stakeholders, including the unregulated private sector; new thinking is needed to identify incentives and sanctions that work best in the private sector ([404](#), [712](#), [1081](#)).

5. Monitoring how well childhood infections are treated is possible with small datasets and/or methodological limitations ([107](#), [344](#), [407](#), [408](#), [409](#), [474](#), [703](#), [772](#), [1022](#)). However, it is crucial to strengthen the quality of data that inform policy decisions about children's medicines in LMICs. Periodic evaluation of efforts to improve medicines access and use for children is essential ([434](#), [635](#)).

6. Evidence about the effectiveness and costs of strategies to improve access and use of medicines for children should be summarized, and the results should be disseminated and used by decision-makers and program managers ([144](#), [307](#), [488](#), [709](#), [1210](#)).

7. Continuous monitoring, evaluation, and feedback should be part of Integrated Management of Childhood Illness (IMCI), and indeed should apply to the entire health system to encourage quality ([416](#)).

8. Community capacity development through education, full participation, and supervision of community health workers in integrated Community Case Management (iCCM) should be encouraged; supervision of supervisors is essential and incentives need to be carefully considered to ensure sustained quality of care and motivation ([199](#), [633](#), [635](#)).

Key Research Recommendations

More research is needed to:

1. Address critical knowledge gaps in the neglected areas of medicines for chronically ill children as well as neonatal and adolescent age groups ([831](#)).

2. Investigate factors affecting supply and demand for pediatric formulations ([404](#), [784](#)). More research is needed to address shortages of pediatric formulations for essential medicines and to encourage the development of quality pediatric medicines/formulations ([404](#)).

3. Identify how to effectively engage the unregulated private sector on the issues of medicines for children and pediatric formulations of essential medicines.

4. Assess the impact on health outcomes of strategies targeting the quality improvement process and incentive systems as they relate to children medicines. In the context of continuous quality improvement, how to encourage education and supervision of practitioners in a setting of multiple competing priorities and low allocation of resources?

5. Evaluate the reasons for unnecessary use of medicines (e.g., antibiotics) and non-adherence to needed medicines (e.g., anti-epileptics) in children.

Medicines for Malaria

Theme 10 - Expanding Access to Appropriate Malaria Treatment through Public and Private Sector Approaches

Introduction

The scaling up of malaria prevention and control measures, including widespread use of bed nets, better diagnostic tools and availability of effective medicines to treat malaria, has led to a decline in estimated malaria cases and deaths over the past decade. A central theme of ICIUM malaria sessions was the importance of involving both public and private sectors in efforts to expand access to Artemisinin Combination Therapy (ACT) and use of Rapid Diagnostic Tests (RDT). Key points presented during the Conference were:

1. Both the public and private sectors (including licensed chemical sellers and the retail market) have critical and important roles to play in improving access to ACTs (312, 434, 712, 921, 1214).

2. ACTs are currently more accessible in the public sector. When available in the private sector where healthcare financing is largely out-of-pocket, they tend to be more expensive (434, 704).

3. Ineffective and cheaper antimalarial monotherapies are still predominant in the private sector, largely due to lacking or ineffective regulatory systems (113, 312, 1081, 1146, 1301).

4. Home-based care without the use of RDTs could lead to over-estimation of malaria prevalence and over-usage of ACTs. (267)

5. The capacity of the private sector to manage malaria effectively is very weak. The adherence of public health workers to treatment guidelines that take into account diagnostic test results is generally poor (113, 126, 241, 439).

6. When community health workers are committed, appropriately trained, supported, and well equipped, the use of RDTs to determine the need for ACTs in community case management of malaria has been found to be feasible, acceptable, and effective in reducing over-use of ACTs and malaria burden (314, 746, 835).

7. Effective pharmacovigilance systems in both the public and private sectors are essential to detect adverse drug reactions to ACTs and other antimalarials. However such systems are currently weak (714).

Policy and Program Recommendations

1. The use of ACTs and RDTs should be scaled up in public health facilities, in the private sector, and at the community level in all countries at high risk of malaria (314, 746, 835, 1095).

2. Strategies to encourage and improve health worker adherence to treatment guidelines for malaria should be adopted by countries (132, 241, 439, 704, 834).

3. National Malaria Control Programs and Ministries of Health must fully engage the private sector to ensure an effective and comprehensive implementation of antimalarial policies. Pragmatic interventions should be directed toward medicine outlets and their practitioners to enhance their contribution toward scaling up effective treatment of malaria (113, 712, 921, 1081, 1214, 1301).

4. There is a need for enforcing regulations to ensure that monotherapies and ineffective anti-malarials are completely removed from the market (312, 704, 754).

5. The private sector needs to be supported, regulated, and supervised effectively to ensure that it contributes to improving access to ACTs (434, 1081, 1137). Licensed drug sellers should undergo adequate training (especially in relation to treatment guidelines, patient counselling, business and stock management), and gain better access to credit facilities.

6. Countries should implement sustainable strategies to ensure affordability of ACTs in the private sector (704, 712).

7. Pharmacovigilance systems should be strengthened in the public and private sectors (714).

8. Data related to services from the private sector could be collected and incorporated into the National Health Management Information Systems to assist in decision making (1081).

Key Research Recommendations

Further research is needed to:

1. Test interventions aimed at improving health worker adherence to treatment guidelines for malaria and appropriate use of RDTs.

2. Investigate options for deploying ACTs more effectively in the private sector.

3. Explore mechanisms for improving affordability and quality of ACTs supplied in the private sector.

Medicines for Tuberculosis

Theme 11 - Improving Availability and Appropriate Use of TB Medicines

Introduction

ICIUM tuberculosis (TB) themes focused on TB medicines supply and TB case management:

1. In many countries, supply chains of TB medicines are deficient, and frequent medicines shortages hinder the control of TB (1068, 1102). Effective information systems integrating medicines supply and stock control with case notification and management as well as epidemiological surveillance have shown encouraging results in strengthening TB programs (1053). Electronic tools to calculate TB medicines consumption at different levels in the health system facilitate medicines supply management (1083). A training program in TB medicine supply management targeting the nurses of primary health care facilities in South Africa resulted in improved TB stock management (1113).

2. The lack of pediatric formulations of TB medicines and inadequate adult formulations remains a major challenge in resource limited settings (1022, 1317).

3. The majority of patients with TB seek treatment in the private sector where they often obtain TB medicines without prescription (946, 1094, 1317).

4. The high burden of TB among HIV-infected individuals underlies the importance of TB diagnosis, treatment, and prevention in HIV care. Many co-infected individuals are in need of concurrent ART and TB medicines, raising the issues of drug interactions, shared drug toxicities, and TB immune reconstitution inflammatory syndrome (IRIS) (486, 792).

5. Limiting the presence of anti-TB medicines to primary health care clinics in rural areas, primary health care hospitals in urban areas and community-based DOT has been shown to prevent non-adherence to TB medications (1053)

6. Management of children with TB remains a challenge. The main areas of concern are limited availability of pediatric formulations, poor clinical management, co-infection with adults, and challenges associated with treating children with MDR-TB (1022).

Policy and Program Recommendations

1. Medicines supply mechanisms at the national level should be transparent, so that countries can address funding gaps and quality assurance issues in partnership with global medicines supply facilities (1050, 1102, 1110).

2. Proper information systems that allow for rapid extraction of key data and epidemiologic reports are critical to quantify the extent of medicines shortages and to identify their causes,

so that action can be rapidly taken and resources strategically allocated (596, 667, 792,1053, 1068, 1083,1122).

3. Policy makers should mobilize to align national regulations on TB medicines with global WHO recommendations; existing regulations preventing the OTC sale of TB medicines should be enforced (1039, 1094).

4. Governments should facilitate further systematic operational research, especially in the private sector, to build evidence about effective regulatory interventions.

5. Training programs on TB management should reach out to staff in private pharmacies and to community leaders (395, 946).

Key Research Recommendations

Further research is needed to:

1. Investigate determinants and predictors of successful TB treatment among different populations and levels of health care (953).

2. Study the risks/benefits and cost-effectiveness of multidrug regimens of shorter duration in TB management.

3. Evaluate strategies to improve adherence, such as shorter multidrug regimens and/or supervision of preventive treatment, particularly in children who are at high risk to progress to disease following exposure (344).

4. Assess the value of new technologies to support interventions targeting patient adherence to treatment (1078).

5. Measure the effectiveness of models that integrate community health workers in the management of TB patients and the feasibility for scale up.

Medicines for HIV/AIDS

Theme 12 - Challenges Associated with Antiretroviral Therapy

Introduction

The following are key findings about antiretroviral therapy (ART) presented during ICIUM:

1. Applying international benchmarks during national tenders for antiretroviral medicines (ARVs) helps achieve optimal pricing (1159).
2. Strengthening operations management in public health care facilities is essential to improve patient outcomes and reduce loss of follow-up (1244).Evidence indicates that simple interventions targeting paper-based patient appointment and tracking systems in health care facilities have positive effects on ART adherence (505, 532, 542, 543, 544, 817, 1121).
3. Because of limited availability of pharmaceutical professionals, health care workers counsel patients and dispense ARVs: their continuous mentorship and training is paramount to improving patient management (378, 1125) and compliance with treatment guidelines (1092).
4. Patient health literacy programs are effective in maintaining successful outcomes (930).
5. New technologies may assist in facility and patient management. Mobile electronic tools with integrated functions facilitating patient appointments, dispensing, managing stock, and monitoring adherence through pill counts, show promising results (985, 990, 1163). M-health interventions such as telephone alerts may improve adherence (744, 876, 889, 942).
6. Monitoring patient adherence to ART with validated standardized indicators remains a challenge across programs and countries (1115, 1172 , 1259).
7. Screening for non-communicable diseases (NCD) risk-factors can be integrated into HIV/AIDS care delivery programs (1162).

Policy and Program Recommendations

1. Low- and middle-income countries (LMICs) should quantify their ARV needs regularly, monitor the occurrence of stock-outs, and use comprehensive approaches to determine the causes of medicines shortages. They should integrate ARV supply arrangements into their national health services structure to ensure the sustainability of ARV provision (217).
2. The performance of public health care facilities with regard to patient follow-up can and should be monitored. To allow for continuous quality improvement, public health care facilities should use an active system for monitoring appointments (e.g., monthly % of

patients attending on or before next appointment, prescription refill indicators) that provide feedback on the facility performance in patient attendance and adherence (1244).

3. Interventions to improve patient adherence to ART need to be multi-faceted. They should include components to strengthen facility operations, secure early adoption of ART guidelines, and guarantee that health care workers undergo continuous training to improve patient counseling and medicines inventory management practices.

4. ART program interventions should be regularly monitored with simple tools and indicators that allow for inter-facility comparisons. Whenever possible, ART programs should take advantage of new information systems for monitoring facility performance, medicines supplies, patient management and outcomes.

5. ART programs should consider establishing a working group to implement and assess quality improvement initiatives with agreed benchmarks (1228, 1229).

6. Strengthening operations management in public health care facilities should be viewed as an essential long-term investment in the quality of chronic care services delivery.

Key Research Recommendations

Further research is needed to:

1. Select ARV scale-up approaches that will ensure sustainable ARV provision; identify factors that contribute to achieving competitive procurement prices in national tenders.

2. Build an evidence base of interventions at all levels of health systems that improve adherence to ART; apply modeling and implementation science methods to design effective interventions.

3. Collect further evidence on the effectiveness, sustainability, costs, and return on investment of m-health interventions in resource limited settings in order to identify cost-effective models for scale up and to decide where scale-up interventions are justified.

4. Evaluate the costs and sustainability of maintaining comprehensive electronic record systems for monitoring facilities, patient cohorts (e.g., children, women), and individual patients; address issues of integration, interoperability, and patient confidentiality when developing and applying electronic tools.

5. Study behavior patterns and the effects of contextual factors (e.g., socio-economic status, social grants, gender) on adherence, treatment progress and outcomes, using interrupted time-series analysis and qualitative research methods. (See Themes 15, 16, and 20) Perform a comparative cost-effectiveness analysis of models which integrate NCD screening and prevention into HIV treatment and care programs.

Antimicrobial Resistance

Theme 13 - Strategies to Combat Antimicrobial Resistance in Health Care Facilities, Primary Care, and the Community

Introduction

The spread of antimicrobial resistance (AMR) meets the definition of a global pandemic and has considerable health and economic impacts for health systems and individuals (538, 1120).Curbing AMR requires coordinated multidisciplinary actions at global/national/local levels (1267, see Theme 17). Because AMR appears to follow antimicrobial (AM) exposure with defined lag periods, systematic surveillance of AM use levels can predict the emergence of AMR and is an important tool in fighting AMR (1142).

Reliable evidence about AM use in many parts of the world, especially low- and middle-income countries (LMICs), is limited in part due to the lack of standardized methods to evaluate AM use. Surveillance studies based on Defined Daily Dose (DDD) methodologies are more informative than indicator-based studies, but more difficult to implement and more expensive (340, 341, 353, 354, 694). Social science qualitative methods, including in-depth interviews, have an important role in studying beliefs about AM use and misuse to treat common diseases and their consequences (115, 319, 489, 584, 713, 729). Inappropriate use of AMs in health care facilities and communities depends on multiple determinants; it is widespread in LMICs, even in countries where antibiotic prescribing is low (366, 384, 386, 526, 556, 582, 668, 702, 742, 766, 796, 866).

Advocacy programs as well as national and local guidelines are critical to improving antibiotic use in LMICs (695, 699, 923). Drug and Therapeutic Committees (DTC), multidisciplinary teams charged with overseeing AM use, and routine quality assurance procedures such as monitoring-training-planning (MTP), pre-authorization, and audits, can improve antibiotic prescribing in health care facilities (291, 471, 778, 793, 919, 1018, 1116). Mixed model approaches targeting policy and advocacy as well as individual behavior changes help achieve success (926).

Policy and Program Recommendations

1. Multi-faceted and sustainable strategies are needed to improve AM use everywhere. At country level, strategies should involve policy makers, civil society, private sector, prescribers, dispensers, and consumers in order to build a coalition and generate widespread advocacy to control AMR, improve AM use, prevent and control infections (509, 1084). An initial "Champion" group for AMR activities needs to act as a catalytic agent, and then step back in order to ensure ownership and engagement by all stakeholders.
2. A national AMR reference center and a national network of local systems should be established. Sufficient resources should be allocated for simultaneous surveillance of AM use and AMR and for adequate microbiological diagnostic capacity at local levels (1057). More funding for research (see below) is needed. Research design and implementation should involve all relevant stakeholders to lead to actionable research outcomes.
3. Countries should develop national antibiotic policies and guidelines that are informed by current evidence from surveillance studies. Standard Treatment Guidelines (STG) and

treatment algorithms should be tailored to local contexts ([194](#), [309](#), [539](#), [572](#)). The intended and unintended consequences of policy changes should be monitored over long periods of time to evaluate their sustainability ([379](#)). Policies should make prescriptions monitoring part of the routine quality assurance process. Policies restricting AM use should target specific AM categories (e.g., broad spectrum AMs) in order to preserve appropriate access to AMs.

4. In all hospitals, multidisciplinary teams including clinical physicians, pharmacists, microbiologists, and nurses should oversee infection prevention and control procedures. These teams should be responsible for developing and implementing local guidelines/ treatment algorithms/clinical pathways of AM use based on national guidelines; they should build community interventions from results of qualitative research and surveillance studies.

5. Interventions should aim at educating health professionals and the public about prevention of infections and appropriate management of common illnesses ([553](#), [868](#), [1054](#), [1206](#)). Schools for health professionals and continuous education programs need to incorporate AMR, infection prevention and control, and rational use of medicines (RUM) into their curricula, from under graduate to post graduate levels. The design and implementation of public awareness campaigns should draw upon available evidence. To have an impact, education programs need be complemented with behavior change interventions ([863](#)).

6. At a global level, principles of ethics should apply throughout the antibiotic production and distribution chains. The public sector and the pharmaceutical industry should partner to facilitate innovation and appropriate use of AMs. Establishing a WHO office with dedicated funding and expertise to support Member States in their AMR activities would help coordinate global efforts. The value of International Health Regulations in controlling AMR should be assessed ([406](#)).

Key Research Recommendations

Research on AM use is needed to:
1. Improve and standardize methods for collecting and analyzing surveillance data on AM use;
2. Investigate the contextualization of AM policies with respect to social norms and behaviors;
3. Translate findings form qualitative research into effective interventions to change behaviors;
4. Identify and disseminate the most effective components of community awareness programs on AM use in order to improve communication strategies;
5. Find strategies to control irrational AM use without jeopardizing necessary access to AMs.

Research on AMR is needed to:
1. Develop and standardize methods for studying AMR (e.g., country-level multi-sector situation analysis tool, diagnostic tools for identification of bacteria resistance [[639](#)]);
2. Investigate associations between AM use and AMR in communities and hospitals;
3. Quantify the consequences of AMR on mortality and morbidity, measure its economic impact on health systems;
4. Evaluate the cost-effectiveness of AMR containment activities, including policy initiatives, to enable priority setting for contextualized and sustainable interventions;
5. Optimize the use of new information technologies in implementing interventions;
6. Study the influence of counterfeit/sub standard antibiotics and antibiotic waste on AMR in humans and in the environment.

Medicines and Health Systems

Theme 14 - Role of Medicines as Part of Health Systems Reforms

Introduction

The positive impact of health care reforms on access to health services and medicines is well documented. The examples provided by Turkey or China are no exception. However, both Turkish and Chinese examples also demonstrate that this positive impact is coupled with a potential increase in medicines expenditures, which would require more emphasis on cost-containment and rational use (959, 1274). The delicate balance between increased access and cost-effective use was illustrated in Dr. Quick's presentation "Universal Health Care Coverage and Access to Medicines: Golden Ring or Trojan Horse? (1243): medicines may be a weak link in health care and health financing reforms, which must be managed with sound policy choices.

Health care reforms are therefore an opportunity to also reform the pharmaceutical sector, make sound choices and introduce the appropriate incentives in the system. ICIUM$_{2011}$ revealed a few opportunities for increased access to medicines, offered by health system reforms in low- and middle-income countries (LMICs):

1. Opportunity for new institutional arrangements for medicines management
2. Opportunity for a more comprehensive involvement of stakeholders
3. A better use of evidence in decision making
4. Opportunity to introduce a new set of core values that will have greater impact on access to medicines, such as Equity or Human Rights.

In formulating new policies and interventions for access to medicines, the complexity of health systems and the multiple and dynamic interactions between system components must be given adequate consideration (1309).

Health system reforms are particularly important to address the increasing burden of chronic care in LMICs, and the role played by medicines in that particular reform is even more important. Health systems of LMICs are generally not equipped to face chronic diseases. In many of them, the pharmaceutical management systems and service delivery models are designed for acute conditions. Same applies for their workforce training and health financing arrangements. There is an urgent need for a chronic care model adapted to resource-constrained settings and that integrates access to medicines (1244, 1245, 1310).

Policy and Program Recommendations

1. Set-up institutional arrangements for a more structured approach to medicines management and rational use, with high-level political commitment and support – following the Omani example (1240).

2. A more comprehensive group of stakeholders (e.g. private and informal sectors, civil society etc.) can be brought on and involved in medicines policy formulation, planning, implementation and delivery of services (918, 1071, 1242).

3. Formulate policies and decisions based on sound evidence; include objective monitoring of impact of policy measures into policy design and implementation from the outset (883, 1202).

4. Endorse Equity as a core value of the reform, collect and analyze population-based data to inform sound policies, with adequate consideration of socio-economic and cultural and community determinants of access to medicines (794). Use this evidence and knowledge to design community-level interventions more effectively.

Key Research Recommendations

Further research is needed that focuses on the following questions:

1. How to develop national integrated health systems approaches to promote appropriate medicines use and how to monitor policy implementation (1265)?

2. What is the impact of medicine management strategies developed by health insurance systems in LMICs (213, 236)?

3. How to assess contents of medicines policies with a focus on equity outcomes, for example (but not limited to) gender equity (1246)?

4. Develop methods to investigate community perspectives on access to medicines, building on knowledge from other disciplines such as sociology and anthropology, for an in-depth understanding of patients and community needs. (1316, 1317, 1318)

Theme 15 - Medicines and Vulnerable Populations: Approaches toward Gender Equity

Introduction

1. Systematic reviews and analyses presented during ICIUM$_{2011}$ offered little evidence supporting the existence of gender inequities in medicines access or use. Studies from low- and middle-income countries (LMIC) showed no major differences between men and women, for both adults and children, in regard to health-seeking behavior ([363](#), [854](#)), prescribing and adherence to treatment ([854](#), [1229](#)), or knowledge about antibiotics ([489](#)).

2. Observed gender differences were likely related to dissimilarity in health care needs rather than inequity: women have unique reproductive health care needs and their use of reproductive health services may facilitate r access to medicines ([1246](#)). Medicines use was reported higher among women, which led to higher out-of-pocket medicines expenditure for women ([651](#)). Women were more likely to receive tuberculosis treatment than men ([395](#)). Girls were more likely to receive prescriptions from informal sources of care and boys from doctors or nurses ([854](#)).In another study, men had a 20% higher chance of receiving a prescription with the potential for adverse pharmacological interactions ([266](#)).

3. A study in Nigeria showed that women participating in household decisions were almost twice as likely to access antenatal care from a health worker; these findings highlight the role of poverty and lower levels of education in limiting women's access to health services and medicines ([638](#)).

4. Gender relations played an important role in facilitating access to medicines for both men and women:

   - A peer-to-peer counseling intervention in Nigeria that was successful in increasing male attendance at the support groups for people living with HIV/AIDS was also associated with increased rates of partner disclosure and testing ([365](#)).
   - The implementation of a Prevention of Mother-to-Child Transmission of HIV program in Burkina-Faso faced enormous challenges due to the non-involvement of men ([643](#)).
   - A survey in Thailand showed that males with better knowledge about emergency contraceptive pills were more likely to encourage its appropriate use by their female partner ([664](#)).

Policy and Program Recommendations

1. Pharmaceutical policies related to supply and demand of medicines should be developed with a focus on gender equity; their impacts should be systematically monitored and evaluated by gender and by socio-economic status (1246).

2. Pharmacists need to be educated on the appropriate use of medicines for women and on how to counsel clients on women's health issues (816).

3. Men should be counseled and educated about women's reproductive health needs in order to facilitate access to and use of reproductive care and medicines by women.

4. Policies should aim at reducing the impact of poverty and insufficient education that disproportionately affect women. This can be done by increasing government funding for health care, providing health insurance/subsidies for women and children, increasing community awareness and age-appropriate reproductive health education for women and girls, and enacting policies to promote women's participation in household decision making.

Key Research Recommendations

1. Further research is needed to investigate gender equity in medicines access and use within countries, with a focus on countries with known political, social, economic, and educational gender inequities. Of particular relevance are the following research areas:
   - Understanding how gender affects quality of care and the relationships between medicines prescribing, medicines access, and health outcomes.
   - Studying complex interactions between gender and economic, social, cultural, and other factors that impact patients' need for, access to, and use of medicines. This will require methodological advances in gender research.

2. Researchers can use several sources of information to investigate gender inequity in medicines access and use such as administrative (insurance claims) and clinical (medical records) data, IMS Health prescribing data, household and facility survey data. Data on patient outcomes will increasingly become available through new information technology systems.

3. In the analysis of medicines programs and policies, it is important to explicitly assess gender effects rather than controlling for them.

4. Gender research about medicines in HIV/AIDS, TB, and malaria is dominated by access studies in HIV/AIDS in sub-Saharan Africa and Southeast Asia (640). More research about gender differences in medicines access and use is needed in other regions.

Theme 16 - Medicines and Vulnerable Populations: Approaches toward Socioeconomic Equity

Introduction

ICIUM presentations underscored the relations between lack of medicines access and:

1. **Poverty** - Because of lack of health insurance, medicines are mostly financed by out-of-pocket payments in low and middle income countries (LMICs). Results from household surveys conducted in several LMICs confirmed that income is a key predictor of access to medicines ([265](), [293](), [970](), [1035](), [1089]()). Spending on medicines disproportionally burdens the poor and the high cost of medicines can push large groups of patients into poverty ([173]()).

2. **Rural settings** - In several countries, households from rural areas were less likely to access medicines ([970]()); and in Ghana they were more likely to use traditional medicines ([265]()). In Barbados, the poor live in rural areas that are farther from health facilities ([1089]()). When distance to the clinic could be minimized, adherence to treatment could be improved ([1229]()).

3. **Lack of education** - Higher education predicted better access to medicines ([293](), [970]()).

4. **Age** - The elderly were at risk of using potentially inappropriate medicines ([1190]()), and chronically ill children particularly vulnerable when families faced financial burdens ([144]()).

5. **Gender** - See Theme 15

6. **Lack of health insurance** - Evidence shows that health insurance improves access to and use of medicines ([236](), [1034](), [1165]() and see Theme 18). However,

    *   Insurance schemes tend to target the employed and wealthy first, not the poor ([213]()). The integration of multiple insurance schemes to ensure equitable health coverage for the entire population presents multiple challenges. Rising costs, especially for medicines, threaten the sustainability of universal health insurance systems ([1243]()).

    *   Policies to provide medicines and health services free of charge (or at reduced prices) to socially vulnerable groups only improve access to medicines if medicines are available in public health care facilities ([697]()).

    *   An analysis of court actions about pharmaceutical assistance in Brazil suggested that free distribution of essential medicines does not always prevent socioeconomic inequities in medicines access ([679]()).

7. **Lack of availability of lower-cost, quality generic formulations of essential medicines in public health care facilities**, often associated with inadequate and outdated national essential medicines lists ([293](), [933](), [941]()).

Policy and Program Recommendations

1. Health care and pharmaceutical policies should be developed with a focus on socio-economic (SE) and gender equity; their impact should be systematically monitored and evaluated by income, education level, age, gender and geographical region to ensure that they do not negatively affect vulnerable populations (1246).

2. Social predictors of poor access to medicines, such as root causes of poverty, low levels of education, urban/rural disparities must be addressed in parallel to reducing financial barriers to medicines. Multi-stakeholder collaboration involving governments, NGOs and civil society, academia, and research-based and generic manufacturers is urgently needed to improve medicines access for the poor (1239). Much advocacy is needed to make the general population, especially the poor and disadvantaged, aware of their health rights.

3. Based on the positive results achieved with accredited drug dispensing outlets (ADDOs), initiatives that leverage current sources of health care for rural populations, such as drug sellers and faith-based/NGO systems, should be expanded. Mobile or satellite clinics should also be developed to improve access to medicines in remote areas.

4. Systems of risk-protection for low-income and vulnerable populations via universal health insurance schemes and/or adequate public health systems should be developed and structured to ensure equitable access to quality medicines.

5. It is critical to improve access to and use of quality generics. This requires concerted efforts by governments to develop and implement an essential medicine policy, to guarantee the quality of generics, and to reduce misconceptions about generics through education of prescribers, pharmacists, and patients.

Key Research Recommendations

1. There is an urgent need to evaluate the intended and unintended consequences of policies and interventions targeting affordability and use of medicines by low SE groups and vulnerable populations.

2. More research on the relationships among social factors, such age, gender, culture and ethnicity and their impacts on medicines access, affordability, and use is needed.

3. Research should build on the WHO-HAI Medicines Prices Project foundation to monitor medicines affordability with additional measures (e.g., impoverishment rates, impact of prices by income quartile). Existing validated measures of economic burden of health care and medicines expenditures should used and further refined (276 and see Theme 6).

4. Results of research on issues related to appropriate prescribing, adherence to treatment, and health outcomes should be stratified by SE status.

Theme 17 - Role of the Pharmaceutical Industry in Medicines Access and Use

Introduction

For the first time, the pharmaceutical industry was invited to participate in ICIUM with the objective of enabling constructive dialogues among all groups concerned with access to medicines in low and middle income countries (LMICs). The following key points were raised:

1. Pharmaceutical companies, including generic manufacturers, are stakeholders in medicines issues. Their initiatives and partnerships to improve medicines access are guided by corporate responsibility principles (541, 634, 825, 1037, 1044, 1057, 1239, 1245). The most effective tools that they can proactively apply to benefit the public are market segmentation and differential pricing, voluntary licensing, comprehensive patient access programs, and long term donations (1291). Pro bono research, management support (human resources, technology transfer), and constructive use of patent libraries are also part of the corporate responsibility "tool box' to improve access to medicines (1239).

2. The increasing recognition that market failures are a reality calls for new business models, such as pooled R&D funding mechanisms and Product Development Partnerships (PDP) which are intended to address the industry disinvestment in R&D for antibiotics and medicines/vaccines for neglected diseases (541, 972, 1011).

3. The marketing policies and practices of pharmaceutical companies lack transparency, and LMICs have particularly weak regulations in this regard (411, 599, 924). Training can help nurses and communities critically assess promotional activities (146, 510). Great political will, strong ethical standards, and regulatory authorities are required to develop practical and implementable policies to control pharmaceutical marketing (193, 509, 934, 1093).

4. The Access to Medicine Index (ATMI) is a potentially useful tool to monitor the impact of pharmaceutical companies on access to medicines in LMICs. It promotes information dissemination and dialogue, enables comparisons among participating companies through standardized metrics, and helps highlight the industry contributions to medicine initiatives (270, 600, 1288, 1291). In its current form however, the ATMI lacks a clear conceptual framework, does not capture patients perspectives about medicines access, relies on self-reported data, and its resource-intensive methodology has not yet been validated (1289).

Policy and Program Recommendations

1. Multi-stakeholder collaborations are needed to improve access to and use of medicines for vulnerable populations (1025, 1058, 1242). A small group of responsible actors representing all stakeholders in medicines access should create a global and independent think-tank with

the objective of identifying win-win collaborations on specific issues (1239). Partnerships that include the pharmaceutical industry must achieve equal balance of power among stakeholders so that all feel empowered; for example, pooled funding mechanisms should include expertise and abilities from LMICs (972, 1011).

2. In order to facilitate innovation and appropriate use of antibiotics, there is need for a new global compact involving all stakeholders to establish a new business model for antibiotic development in which financial return is decoupled from sales volume (1267).

3. The pharmaceutical industry should consider provision of funding to address problems related to medicines access and quality of care. This funding could take the form of a to-be-defined percent of profits devoted to these activities. (See Summary Plenary 4)

4. Pharmaceutical companies should stop advertising inappropriate use of medicines (1265). Greater awareness of positive and negative consequences of promotional activities is needed through education and training of all stakeholders, especially vulnerable communities, civil society organizations, and health workers (146, 411, 510).

Key Research Recommendations

Research is needed to address the following:

1. How to identify a core set of best practices for pharmaceutical companies that improve access to medicines (1239, 1265)?

2. How do public-private partnerships affect investment, product development, relationships between stakeholders, and pharmaceutical distribution (1247, 1267)? Which pooling approaches are effective in increasing pharmaceutical R&D funding (972, 1011)? What is the impact of new business models to promote development and controlled distribution of new antibiotics? How to encourage the development of quality pediatric formulations (404)?

3. What is the long term impact (sustainability, knowledge, skills, behavior) of education about promotional activities in the community and among health workers (146, 246, 510)?

4. With regards to the ATMI methodology, how to develop and validate a small set of core indicators to enable annual comparisons and longitudinal analysis; collect evidence to fill data gaps on pharmaceutical marketing/promotional activities; integrate patients' perspective about medicine access; and make ATMI an open-source, information hub for submitting and collating data on medicine access?

5. How to investigate and disseminate the underlying components of price (such as the cost of manufacturing, recovering R&D costs, ongoing marketing costs, taxes) to promote greater price transparency (See Themes 6 and 7, 287, 747, 883, 904)?

Theme 18 - Health Insurance and Medicines Access, Affordability, and Use

Introduction

Medicines account for up to 60% of total health expenditures in low and middle income countries (LMICs) and constitute a major source of inefficient spending.[1] Health insurance has the potential to improve medicines access, affordability, and cost-effective, appropriate use. Health risk protection/insurance schemes are expanding and a global movement is underway toward universal health coverage (UHC), with some LMICs close to achieving UHC.[2,3] Evidence on medicines coverage in LMICs is limited (186).

1. Health insurance often does not cover medicines (819). Providing medicines coverage improves access to medicines and increases utilization (236, 307, 528, 1034, 1047), although not necessarily for the most vulnerable populations (213, 957, 964, 1158).
2. Insurance systems that provide medicines coverage can control the use of medicines by their members with strategies targeting (236, 1243):
    *   Contracts with providers: in Thailand, capitation and case-based payments to providers are associated with less prescribing of new, expensive, branded products (718) and of products not on the national essential medicines list (811) than fee-for-service (FFS) payments. Direct FFS payments to hospitals may be associated with higher medicines utilization than patient reimbursement of medicines expenses (1004).
    *   Medicines selection and purchasing: the use of formularies based on Standard Treatment Guidelines is a critical cost-containment tool (1126).The use of external reference pricing by national health insurance can improve medicines access (965)
    *   Medicines utilization management includes incentives for quality, the separation of prescribing and dispensing, education of providers and consumers, and disease management (320, 1009).
3. Active medicines management strategies are rarely used in LMICs, and the lack of sound medicines coverage policies threaten the viability of health insurance systems (1243). Some data to evaluate impacts of medicines coverage policies exist in insurance systems; however they are not used routinely for monitoring and evaluation (213, 1191).
4. Different management strategies can be combined to increase the use of generics (279).
5. Major problems reported by insurance schemes in Africa include provider payment delays and concerns about fraud and abuse (213).
6. For innovative medicines, pharmaceutical companies are exploring novel value-based pricing and risk-sharing arrangements with health insurance schemes, based on utilization volume, health outcomes, patient risk, adherence, or affordability (281, 1308).

Policy and Program Recommendations

To improve medicines access and appropriate use, insurance programs should (213, 1243):

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[1] WHO. World Health Report 2010: Financing for Universal Health Coverage. Geneva: WHO, 2010.
[2] The Rockefeller Foundation. Catalyzing change. The system reform costs of universal health coverage. New York: The Rockefeller Foundation, 2010.
[3] Joint Learning Network for Universal Health Coverage

1. Cover *"smart" therapeutics (*i.e., essential medicines, medicines consistent with clinical guidelines, outpatient medicines); and *incentivize appropriate use* through medicines coverage policies that favor products with a high therapeutic benefit/risk ratio.
2. *Strive toward increased efficiency* through policies for generic and therapeutic substitution, and efficient systems for procurement, inventory management, distribution, medicines use review, and fraud detection.
3. Connect medicines financing with reliable health care facilities and *sources of medicines* such as accredited health providers and dispensing outlets.
4. *Strengthen human capacity, build data systems, and define standard indicators* for routine monitoring and evaluation of medicines coverage policy effects and for defining and implementing policy changes based on evidence.
5. *Establish an objective evaluation system and a culture of adaption* with routine monitoring, evaluation, and improvement based on what is and is not working, involving relevant disciplines (medicine, pharmacy, pharmaceutical management, economics, financing, accounting, law, ethics, information technology) to ensure that the insurance scheme is inclusive, facilitates high quality care, and ensures timely reimbursement to health facilities and patients.
6. Strive toward *universal coverage,* with a focus on vulnerable populations, and with provision of medicines benefits, while monitoring expenditures, particularly on medicines, which can threaten the sustainability of the system.
7. *Develop a network of key in-country stakeholders* who are interested in developing universal health insurance coverage and ensure that medicines are covered adequately. This network could serve as a centralized portal to share literature and experiences on medicines coverage from LMICs.
8. *Educate patients, providers, politicians, lawmakers, and the public* about cost-effective, appropriate use of medicines.

Key Research Recommendations

Using appropriate research designs, researchers should focus on ([1243](#)):

1. How to design *minimum medicines benefit packages*; what pieces of baseline information to assemble, which options to consider and which criteria to follow; how to implement different medicines coverage management strategies and how to prevent inefficiencies.
2. The *key contextual factors* (i.e., political, economic, social) *for different medicines coverage approaches* in health insurance programs of LMICs.
3. The *impacts of specific medicines coverage policies* on:
   - Equity in medicines access, cost, and affordability; appropriate use of medicines; health and economic well-being of populations; patients and providers satisfaction;
   - Economic sustainability of UHC/risk protection schemes.
4. How to cover *innovative high-cost medicines* that may provide substantial benefits to few individuals only; how to measure the effects of innovative pricing and reimbursement strategies on medicines use and cost, and on health outcomes.
5. How to create a *medicines coverage-focused network* that collects and assembles evidence in a systematic way to facilitate the sharing of experiences across LMICs.

Evidence for Pharmaceutical Policy Decision-Making

Theme 19 - Approaches to Pharmaceutical Sector and Stakeholder Assessments

Introduction

Vast amounts of information may exist about country pharmaceutical data, but the information is often not collected in a standardized manner, fragmented or not easily accessible, despite legal obligations for data disclosure and transparency in many countries.

It is recognized that the challenges around medicines access and use are too complex and multi-factorial to be solved by one stakeholder – multi-stakeholder collaboration is urgently needed. Programs such as the Medicines Transparency Alliance (MeTA) and a variety of public-private partnerships have made efforts to bring different constituencies around the table to identify the potential for shared objectives, for disclosure of good quality information, and to negotiate interests more actively and transparently (1025, 1242).

Application and availability of the MeTA/WHO/Harvard survey tools such as pharmaceutical sector scan (502, 967), data disclosure survey (977, 1257), household and facility surveys (1035), multi-stakeholder assessments (1108), and the WHO/Global Fund pharmaceutical country profiles (1258) have made standardized, transparent, and validated information about the pharmaceutical situation publicly available in several countries (1013, 1258).

Working consistently within a multi-stakeholder group of government, private sector, civil society and academia creates trust, promotes disclosure of 'robust' information on the pharmaceutical sector and the medicines supply chain within a health system. This enables joint discussion, analysis, validation, and ownership (1025), with the ultimate aim of improving accountability and access and use of medicines.

Policy and Program Recommendations

1. Sensitive data and ownership in the medicines supply chain should be discussed in a multi-stakeholder group of government, private sector, civil society and academia to facilitate joint ownership, transparency and ultimately improved accountability (1025, 1242).

2. There are multiple stakeholders even at the health care delivery level, and mechanisms exist to include them and improve performance (e.g. DTC, ADDO, etc.). All stakeholders should make more resources available for multi-stakeholder processes and pharmaceutical programs across sectors, but also at all levels of the health system.

3. It is important to ensure a good balance of relevant stakeholders in round tables on access to medicines, so that all are empowered (1025, 1108, 1242).

4. All countries should perform regular standardized surveys on their pharmaceutical situation to enable monitoring of progress towards transparency and access to medicines, as well as to identify deficiencies in health information management where data is simply not collected or fragmented. This information should be widely disseminated as a means of improving accountability in the pharmaceutical sector and at all levels of the health system.

5. Cross-country analysis of data from standardized surveys such as the pharmaceutical sector scan on price, quality, availability, and promotion of medicines (967, 1299) identifies how countries compare in the extent of data disclosure and highlights areas of similarity and differences, but also reveals some methodological interpretation differences. Surveys and questionnaires should pay attention to providing clear explanations and should include technical validation by experts.

6. National validated data from standardized surveys should be collated and compared in regional and/or global reports for benchmarking and analysis (1258, 1299).

Key Research Recommendations

Designing multi-stakeholder processes and measuring their effectiveness is a new approach to improving information on the supply chain and use of medicines. It poses considerable challenges and is a rich field for future research.

1. The MeTA multi-stakeholder assessment methodology will benefit from further field-testing and refinement beyond the 5 MeTA pilot countries it was applied in (1108).

2. Several key questions remain unanswered. How to address the reality of power imbalances in a multi-stakeholder approach – Governments, donors, private sector, civil society constituencies? How can potentially sensitive data best be disclosed? What data can medicines regulatory agencies make routinely and transparently available on their websites, and what should be kept confidential?

3. The next phase is to move from data collection to analysis and use – the strength of the multi-stakeholder approach needs to be tested.

4. More research is needed on the 'gap' between availability of information and how it can be used to change pharmaceutical policies within a health system to improve access to medicines.

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Theme 20 - Longitudinal Data and Methods for Policy Evaluation

Introduction

It is vitally important to evaluate the impact of pharmaceutical policy changes on important outcomes such as the use and cost of medicines. When conducting these evaluations, it is very important to use rigorous methods to avoid the many potential sources of bias that can result in incorrect policy assessments.

Interrupted time series (ITS) is one of the most feasible and rigorous longitudinal designs for measuring changes in outcomes after implementation of pharmaceutical policies ([1249](#)). These methods control for pre-existing trends and other common biases to validity, and they can be used to infer causality when interventions result in detectable changes. Further, the impact of pharmaceutical policy changes on time-to-event outcomes can be rigorously evaluated using survival analysis.

Policy and Program Recommendations

To promote the rigorous evaluation of policies to generate strong evidence about their impacts, countries are advised to follow these recommendations:

1. Whenever possible, policy changes should be evaluated to assess their impact on medicines use, medicines costs and health outcomes. Due to widespread success in demonstrating intended and unintended impacts of pharmaceutical policies and interventions, longitudinal designs and statistical methods should be used when data is available. The use of weaker designs (pre-post or post-only policy evaluations) are subject to many common threats to validity, provide much weaker evidence of policy impacts, and cannot usually be used to infer causality.
2. Resources should be included in every policy implementation to conduct a longitudinal policy evaluation. Policy actors (national agencies, health systems, donors) should incorporate the use of longitudinal policy analysis as part of routine operations.
3. Longitudinal policy evaluations should be planned in advance in collaboration with policymakers, so that policy implementation, data collection, and statistical analysis methods can be coordinated. Retrospective policy evaluations are often possible, but often more difficult to design and may be limited by data availability.
4. Training programs should be established to introduce use of these methods to program analysts and academics in low and middle-income countries. The statistical methods for interrupted time series and survival analysis are well within reach of researchers with intermediate statistical training.

Key Research Recommendations

Recommendations for the conduct of longitudinal research

1. Longitudinal studies can use a wide variety of sources of routine data, including pharmacy records, electronic prescribing data, clinical data extracted from electronic medical records, and insurance system administrative claims data. While resource intensive, it is also

possible to use manually collected data from paper records in health facilities to do longitudinal policy research. Examples of studies presented at ICIUM$_{2011}$ included market utilization and sales data ([379](#), [716](#), [878](#), [910](#), [998](#), [1034](#)), insurance plan claims data ([514](#), [1165](#)), electronic medical record data ([1118](#)), hospital pharmacy data ([471](#), [539](#), [542](#), [811](#), [1004](#)) and manually extracted routine data from clinics ([505](#), [516](#), [817](#), [1121](#)).

2. Graphical displays of longitudinal data as ITS or survival plots are a key to detecting data quality problems and also to presenting results to policymakers. They should be used at all stages of data cleaning, analysis, and presentation of results.

3. When comparison series are available (e.g., other groups or related behaviors not subject to a policy), ITS and survival analysis can provide even stronger evidence about policy impacts.

4. ITS designs are best suited for evaluating change after single interruptions or interventions where effects are immediate. However, they can also accommodate anticipatory changes or lagged effects. When sequentially implemented policies are separated by a sufficient number of periods, it is possible to separately estimate their impacts. Such methods are well-validated.

5. ITS designs typically perform best when there are 12 or more periods before and after a policy interruption. However, many outcomes (e.g., percentage antibiotic use for ARIs) are typically stable over time, and ITS can accommodate segments as short as 6 months.

6. Obtaining data for longitudinal research often requires cooperation from health system or facility administrators. As an incentive for their cooperation in receiving data, it is important to provide the institutions providing data with graphical displays and analyses tailored to their particular needs (e.g., differences between facilities or peer comparisons). This can promote a culture of monitoring and evaluation.

Areas for methods development and more research

1. More longitudinal research is needed on the health outcomes of pharmaceutical policies. These studies are most feasible using routine data sources that include more detailed clinical information (e.g., linked hospital databases or electronic medical records).

2. Little is known about the cost-effectiveness of pharmaceutical policies. Frequently routine administrative data contain information on service costs that can contribute to cost-effectiveness studies. Researchers must be careful to use financial information carefully in cost-effectiveness research since costs can be different across facilities or across patients with different insurers.

3. More multi-disciplinary, multi-method methods are needed for evaluation in situations where multiple pharmaceutical policies are implemented in rapid succession in complex environments. These would involve more advanced methods for longitudinal analysis of routine data, as well as document review, qualitative, and survey methods. This is an important area for development of best practices.

Theme 21- Household Surveys to Evaluate and Monitor Pharmaceutical Policies

Introduction

Geographic, economic, cultural, and educational barriers to obtaining and using medicines appropriately can only be measured at the household level. Household surveys on medicines provide a unique source of information for policy makers about care-seeking, perceptions and attitudes about medicines, as well as medication affordability and use in the community. Over forty ICIUM$_{2011}$ presentations and posters presented results from household surveys (many conducted with the WHO/MeTA methodology[4]), highlighting the value of these surveys in low- and middle-income countries (LMICs) to:

1. Assess socio-economic and gender inequities in medicines access and use (560, 651, **760**, **854**);
2. Investigate consumer perceptions and preferences about medicines (488, **1223**), storage of medicines at home (318, 1061), self-medication (319, 762);
3. Evaluate the impact on the community of specific policy interventions related to national health insurance (**1047**), medicines reimbursement (697), direct payments for health care (307), changes in antimalarial guidelines (474, **1214**), community education programs (903);
4. Generate information about the actual utilization of antibiotics (129, **386**, 694, 742) and of traditional medicines (265) in the community; about the utilization and affordability of medicines for acute illnesses (**851**, **970**,) and chronic diseases (**1208**);
5. Build evidence for the development of a regional pharmaceutical policy (**882**, **1253**), for the implementation of initiatives aimed at improving access to medicines (**1013**);
6. Collect objective data to assess a country pharmaceutical situation (301, 345, 423, 527, **964**, **1035**, **1089**, **1144**, **1147**, **1311**);
7. Address methodological issues associated with survey design (276, **700**, **733**, **1269**).

Policy and Program Recommendations

1. Results of national household surveys on medicines can and should be integrated into policy development especially when policymakers seek to address economic and geographic barriers in medicines access in both the public and private sectors.
2. WHO/MeTA household surveys on medicines are a powerful tool for monitoring the implementation and effects of pharmaceutical interventions within regions and countries, and for informed decision-making. To the extent possible, these surveys should be institutionalized into regular national pharmaceutical situation assessments. Countries are advised to take advantage and cultivate local capacity in order to promote sustainability of this pharmaceutical monitoring process.
3. Teams charged with the design and implementation of household surveys on medicines should consist of individuals who recognize the importance of monitoring pharmaceutical situations in the community, and who have the skills and time to conduct surveys. Teams should be endorsed by all stakeholders in the pharmaceutical sector in order to engender

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[4] http://www.medicinestransparency.org/meta-toolbox/household-facility-surveys-on-access-to-and-rational-use-of-medicines-in-countries/. Studies that used the WHO/MeTA methodology are highlighted in bold.

national ownership of the results. All pharmaceutical stakeholders should be involved in the interpretation of results to increase the likelihood that recommendations are disseminated in a credible and effective way, become consensus, and lead to positive changes.

4. Countries should be able to tailor the WHO/MeTA survey methodology to their own local context, preferably in consultation with WHO/MeTA staff. When countries lack the local capacity to adapt and use the tools, technical assistance in planning, implementing, and analyzing the surveys can build capacity in local institutions for future work.

5. The WHO household survey needs further methodological development to overcome its limitations in design and content, to increase efficiency in administration, and to encourage more immediate use of results by policy makers. (See below)

Key Research Recommendations

1. The WHO/MeTA methodology does not identify "core" household indicators, i.e., indicators that are most relevant to policymakers in LMICs. Filling this gap is an important area of research. It will involve a review of the experience accumulated with the WHO/MeTA methodology, so that an evidence-based selection of core indicators can be proposed and agreed upon by WHO and partners. Identifying core indicators of medicines access and use at the household level will:
   - Reduce both the complexity and costs of the survey by producing a condensed version of data collection tools that focuses on core indicators of medicines access and use;
   - Facilitate the interpretation of core data and the dissemination of survey results in standardized stand-alone reports and in other policy documents such as pharmaceutical country profiles;
   - Inform countries about the minimum amount of data collection required to calculate core indicators;
   - Stimulate policy makers to use the methodology and encourage developers of national household surveys (MICS, DHS) to collect data on core indicators;
   - Provide consistent end-points for cross-sectional and longitudinal survey analyses.

2. The current WHO/MeTA rapid cluster sample survey methodology links households to reference health care facilities on the basis of their geographic proximity, not on the basis of household preferences when seeking care. Research is needed to develop sampling methods that link households with the actual health facilities where they seek care and obtain medicines.

3. It may be possible to take advantage of new technologies to streamline data collection tools (handheld computers, cell phones) and in doing so simplify analysis and reporting tools where appropriate and/or possible.

Research is needed to identify enabling factors and barriers for conducting and using household surveys on medicines. Such information will assist countries in developing an efficient strategy to gather data to monitor community use of medicines and to generate reliable evidence that can be used by national authorities and all other stakeholders in the pharmaceutical sector.

Theme 22 - Monitoring Safety of Medicines - Pharmacovigilance

Introduction

Pharmacovigilance (PV) aims to improve patient safety through the detection, assessment, understanding and prevention of adverse effects and other medicines related problems. Approximately 30 ICIUM$_{2011}$ presentations and posters that were related to pharmacovigilance were accepted for the conference. Many of them presented new indicators or initiatives to enhance pharmacovigilance (1033, 1157, 1175) or described the current situation in middle and low income countries (313, 450, 517, 546, 759, 769, 806, 906, 1135).

The Pharmacovigilance methods session, however, focused on voluntary reporting and opportunities for active surveillance discussing the following approaches:

- Cohort event monitoring (CEM) including patients treated for malaria with artemisinin based combination therapies (580)
- A rapid assessment method for monitoring safety of medicines using a prescription sequence symmetry analysis (200)
- Causality assessment in spontaneous reporting systems
- Other opportunities for active surveillance such as sentinel sites (596 provides an example) and use of social media and SMS.

Policy and Program Recommendations

1. CEM is a useful methodology for evaluating the safety of newly deployed medicines especially on a large scale. It provides rapid safety information and denominator information and is therefore especially useful in settings with weak pharmacovigilance systems.
2. There should be greater use of databases for the detection and confirmation of signals. The prescription symmetry sequence analysis method is illustrating effective use of secondary data in a large database to detect safety issues (hypothesis generating tool).
3. Spontaneous reporting is still the most common methodology for detecting adverse reactions to medicines with notable strengths and limitations. Spontaneous reporting should be strengthened with an additional data stream by encouraging multiple country collaboration especially in poor resource settings with low reporting rates (922 reporting on AZT-based HAART and anemia risk serves as an example of such an additional data stream).
4. The safety of priority medicines used in large populations should be properly evaluated with appropriate PV methods especially in low resource settings and adequate information on the product provided.

5. Pregnancy exposure registers should be developed to capture medicine-related events during and after pregnancy.

6. Newer methods other than spontaneous reporting include targeted spontaneous reporting with focus on a cohort of diseases, use of adverse events cards, diary, social media, web browsing as supported in the FDA and EU documents, and simple SMS systems. Use of these methods should be further explored (see below).

7. Every country needs a pharmacovigilance system, starting with basic functions and supported to grow, especially in low and middle income countries.

Key Research Recommendations

1. The impact of pharmacovigilance activities needs to be assessed with appropriate methodologies. This is to determine the link between investments made and the outcomes obtained.

2. There is a need to identify and develop new pragmatic tools in pharmacovigilance to address gaps in the existing toolkit. The effectiveness of these tools as well as their cost-effectiveness should be established.

3. Existing knowledge base on products used in developing countries is low and specific work is required to provide safety information in view of known differences (e.g. genetic) in the populations.