National Guidelines for Quantification of Narcotic Medicines

Federal Ministry of Health
Nigeria

2017

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RESPONSE TO DRUGS AND RELATED ORGANISED CRIME IN NIGERIA
(FED/2012/306-744) (NGAV16)

NATIONAL GUIDELINES FOR QUANTIFICATION OF NARCOTIC MEDICINES

Federal Ministry of Health

Nigeria, 2017

FOREWORD

The Federal Ministry of Health developed the National Guidelines for Quantification of Narcotic Medicines as part of efforts to address inadequate availability of narcotic medicines for medical and scientific purposes in Nigeria.

Poor quantification has been a major challenge militating against adequate availability of narcotic medicines for medical and scientific purposes with majority of patients in need of these medicines for relief of their pain undergoing untold hardship.

The National Guidelines for Quantification of Narcotic Medicines is therefore developed to standardize the quantification practices and also assure evidence based estimates of narcotic medicines need for medical and scientific use in the country. It contains practical steps to quantify narcotic medicines, guide and facilitate the process of estimating the actual quantities of narcotic medicines required.

The document is a product of extensive work and contributions of a wide range of relevant stakeholders on narcotic medicines including the Technical Working Group on Access to Narcotic Medicines. The quantification tools in the document were piloted in selected facilities across the 6-geopolitical zones; and the final tool was used to conduct the National Quantification of Narcotic Medicines in the country.

I am convinced that the implementation of these Guidelines will lead to a realistic estimate and improved availability of narcotic medicines required for medical and scientific purposes in Nigeria. I therefore endorse and recommend the National Guidelines for Quantification of Narcotic Medicines for use by all facilities and stakeholders involved in the handling of these controlled medicines.

Prof. Isaac F. Adewole FAS, FSPSP, FRCOG, DSc (Hons)
Hon. Minister of Health
Federal Ministry of Health
Nigeria, 2017

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The time, energy and professional expertise contributed by all the members of the Technical Working Group on Access to Narcotic Medicines and other stakeholders in the development of these guidelines is highly appreciated.

The support of members of staff of health institutions where the quantification tools in the Guidelines were piloted is also acknowledged.

The contribution of all involved in the successful development of these Guidelines is equally appreciated.

Osarenoma Clement Uwaifo
Permanent Secretary
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Nigeria, 2017

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ACRONYMS

Acronyms	Meaning
ACPN	Association of Community Pharmacy of Nigeria
COMHPFHI	Committee of Heads of Pharmacy in Federal Health Institutions
FDS	Food and Drug Services Department
DPS	Director, Pharmaceutical Services
EML	Essential Medicines List
FCMS	Federal Central Medical Stores
FDS	Food and Drug Services
FMOH	Federal Ministry of Health
INCB	International Narcotics Control Board
LMCU	Logistic Management Coordinating Unit
NAFDAC	National Agency for Food and Drug Administration and Control
NDLEA	National Drug Law Enforcement Agency
SMOH	State Ministry of Health
TWG	Technical Working Group
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

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EXECUTIVE SUMMARY

Narcotic medicines are among the controlled drugs regulated by the international drug control conventions: the single convention on narcotic drugs of 1961, amended by the 1972 protocol; the convention on psychotropic substances of 1971; and the United Nations convention against illicit traffic in narcotic drugs and psychotropic substances of 1988. They are the mainstay in the management of moderate to severe pain. However, their availability is severely lacking in low to low-middle income countries including Nigeria with the highest burden of disease. Thus, patients endure needless pain that could otherwise be avoided with the administration of these rather cheap but potent medicines.

These medicines are also prone to abuse and illicit use and sometimes associated with crime. In a bid to control its misuse, its availability for therapeutic and scientific purposes are sometimes compromised thus aggravating the already limited supply to patients needing them. The delicate balance between control against illicit use and providing for medical and scientific purposes needs careful attention with the right quantities needed for the later so as not to have excess in the system with potential for diversion.

Whilst mindful of the aforementioned and noting that baseline data is non-existent in Nigeria to inform evidence-based procurement of narcotic medicines to meet disease conditions needing them, this guideline has been developed to facilitate the process of estimating the actual quantities of narcotic medicines required for medicinal and scientific use.

The overarching aim of this national guideline on quantification of narcotic medicines is to standardize the quantification practices in Nigeria and to assure evidence-based estimates of narcotic medicines for medical and scientific use to the INCB.

1. BACKGROUND

Access to controlled medicines for the management of moderate to severe pain is currently inadequate in Nigeria. The Global Access to Pain Relief Initiative (GAPRI) in 2012 reported that Nigeria consumed only 0.1 % of minimum amount of narcotic analgesics required to manage pain in patients who died of HIV/AIDS, terminal cancer, those suffering injuries caused by accidents and violence, some chronic illnesses and those recovering from surgery. These patients undergo untold suffering due to lack of opioid analgesics which can easily control pain. There is therefore an urgent need for the development and implementation of National Guidelines on Quantification of Narcotic medicines to inform a realistic estimate of the country's medical and scientific needs.

Controlled substances such as narcotic medicines have two different potentials: the potential to be used for medical and scientific purposes and to be diverted for illicit use. The dual aim of the international drug control system, under the purview of the International Narcotics Control Board (INCB), is to ensure the availability of narcotics for medical and scientific use while preventing diversion, abuse and trafficking.

The problem of disproportionate levels of consumption between the low and high-income countries has been a matter of concern to the INCB for many years. Access to these drugs continues to be uneven with consumption concentrated primarily in countries in North America, Western Europe and Oceania. Indeed 92 per cent of the world's morphine is consumed by 17 per cent of the world's population while the rest of the world population consumes just 8 per cent. This staggering disparity is cause for concern as it denies many patients including patients in Nigeria the health benefits they are entitled to under the Universal Declaration of Human Rights. Thus, the INCB and the World Health Organization (WHO) made guidelines available that governments can adapt to meet their country's peculiar needs and hence this project to guide quantification of narcotics in Nigeria.

The international drug control regime is based on three international conventions: The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. The 1961 Convention as amended, and the 1971 Convention established control measures for narcotic drugs and psychotropic substances, whereas the 1988 Convention established control measures for precursor chemicals used in the illicit manufacture of narcotic drugs and psychotropic substances. By becoming parties to these conventions, States accept the obligation to implement in their national legislation the provisions of the conventions.

The Federal Government of Nigeria has created two institutions for management of controlled substances in the country. These two institutions are the National Drug Law Enforcement Agency (NDLEA) targeting the illicit use of controlled medicines; and the

National Agency for Food and Drug Administration and Control (NAFDAC), working to ensure that the drugs are used for medical and scientific purposes only.

The European Union funded project "*Response to Drugs and Related Organized Crime in Nigeria*" being implemented by the UNODC from 2013 through 2019 aims to support Nigeria's efforts in fighting illicit drug production, trafficking and use and in curbing related organized crime as well as supporting the Federal Ministry of Health (FMOH) and NAFDAC for improved narcotics quantification and availability for medical and scientific purposes.

2. TRAJECTORY IN THE DEVELOPMENT OF THE NATIONAL QUANTIFICATION GUIDELINES

The development of the national guidelines for quantification of narcotic medicines started in September 2014 as part of the UNODC implemented project. There were many stakeholder consultations including the Technical Working Group, culminating in this final document. The trajectory of its development is detailed in *Annex 1*.

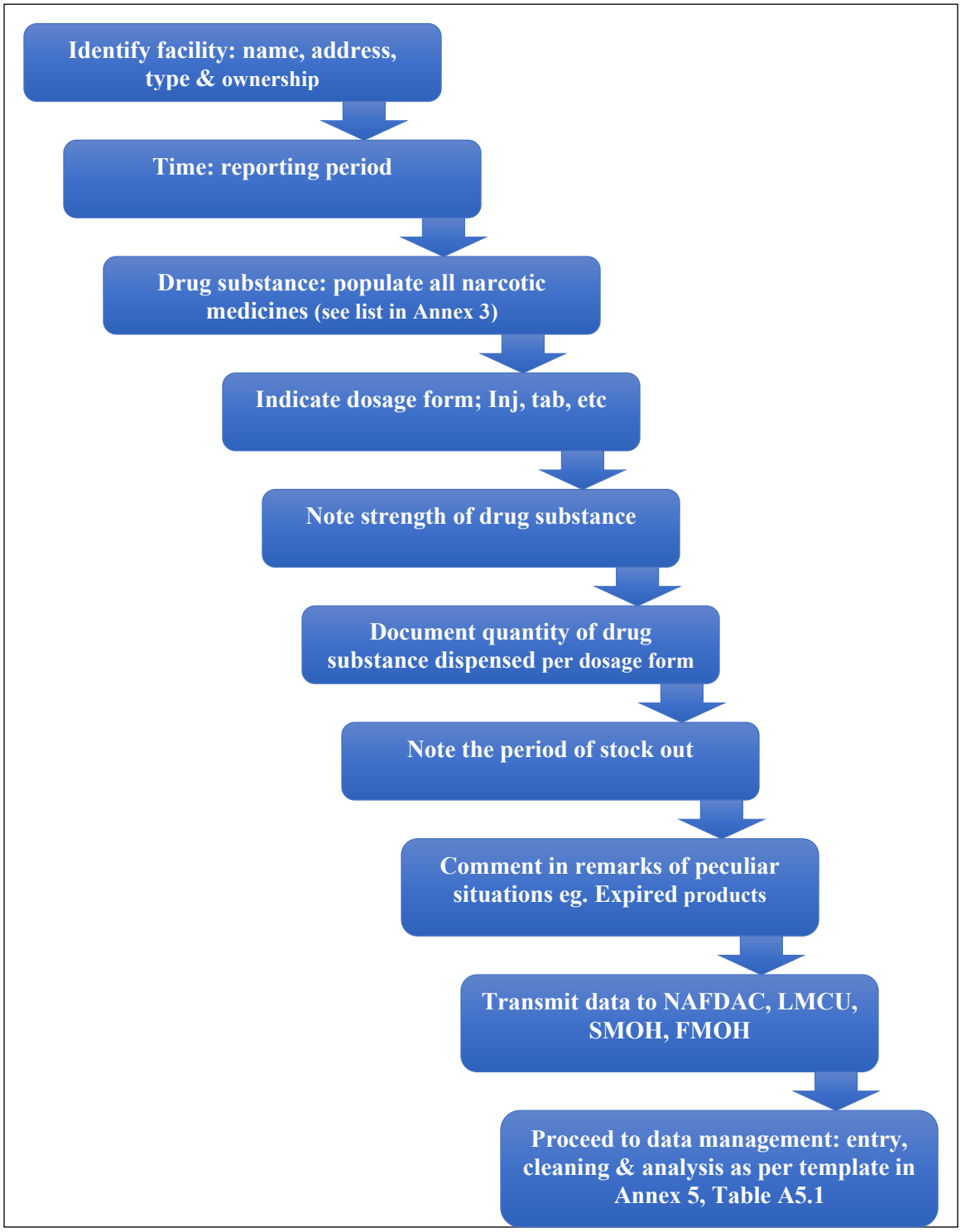
3. GOAL

The overarching aim of the national guidelines for quantification of narcotic medicines is to standardize the quantification practices in Nigeria and to assure evidence-based estimates of narcotic medicines for medical and scientific use to the INCB.

4. OBJECTIVES

- Structure a standard guide for the quantification of narcotic medicines in Nigeria
- Estimate the national need for narcotic medicines for medical and scientific purposes
- Provide evidence-based annual estimates to INCB.

5. THE GUIDELINE



The flow chart above demonstrates the sequence of data identification, collection, transmission and management. Data collection is facilitated using the tools, Form QN 01 (*for health facilities*) and Form QN 02 (*for community pharmacies*) shown in *Annex 3.*

The tool requires the identification of facilities contributing data with full address, type of facility and ownership (private or public). The reporting period must be indicated; e.g. January 1, 2016 to December 31, 2016. Relevant narcotic medicines that were stocked and or dispensed during the reporting period are populated under the drug substance (*see Annex 2*. The formulations are similarly documented on the data collection tool.

The dosage form (*injection, syrup, tablet, etc*) of each drug substance is as well indicated. Subsequently, the strength of corresponding drug substances is indicated. Particular attention must be given to injections, syrups and suspensions. These must be entered thus 5mg/1ml in 2ml ampoule, 2mg/1ml in 50ml vial, 5mg/5ml in 100ml bottle, etc. The total strength per the ampoule, vial or bottle can then be appropriately derived to conclude the drug substance characteristics.

The quantity of the drug substance dispensed per each dosage form during the year under review is captured in the data collection tool. This takes the form; number of tablets, capsules, ampoules, vials, bottles, etc. It is assumed in this circumstance that all dispensed medications are fully consumed. The quantity dispensed per drug substance (*physical count*) and strength (*mcg, mg, etc*) subsequently translates into the "quantity dispensed in mg" for the year under review. The data entry template (*Annex 4, Table A4.1*) auto-computes this and subsequent strengths in grams and kilograms.

It is important to note the period of stock out to assist in computing the average daily consumption extrapolated to annual consumption. Important observations should be documented in the remarks column.

The collated data should be forwarded to the LMCU for entry into the data entry template and subsequently transmitted to NAFDAC and FMOH for further analysis as shown in the narrative following.

6. PROCESS OF QUANTIFICATION OF NARCOTIC MEDICINES

This involves populating the narcotic medicines (*see Annex 2*) prescribed in the country and estimating the quantities consumed.

Selection of Narcotic Medicines:

The first step in quantifying the country's actual requirements of narcotic medicines is to select these medicines from the National Essential Medicines List (EML) developed by the National Drug Formulary / Essential Drug List (NDF-EDL) Review Committee.

The list of prescribed narcotic medicines could also be populated by reviewing books of records in health facilities including patient's records (folders), dangerous drug books, pharmacy and dispensary ledgers among others.

Similarly, the conduct of a small qualitative survey like In-depth Interviews with key informants (Key Informant Interviews - KII) or Focused Group Discussion (FGD) on the subject could reveal a wealth of information on the narcotic medicines used for medicinal and scientific purposes.

Quantification of Narcotic Medicines

The quantities of narcotic medicines can be estimated through the following methods:

i. Consumption-based methods and variants
ii. Morbidity-based method
iii. Service-based method

Either one of these methods or a combination of two can be used in estimating the quantities of narcotic medicines required. However, each method comes with some conditionality's to make it feasible. In the Nigerian situation, the consumption-based method and variants was selected for use.

Consumption-based method and variants:

This approach and its variants are based on use of narcotics over recent years. If past use of narcotic medicines is stable and adequate, future requirements can be calculated by averaging the amounts used in health-care facilities in recent years and adding a margin for unforeseeable increases.

In variants of this method, calculations are based on data obtained from manufacturers, importers and wholesalers that distribute the narcotic medicines to the end users through an established supply chain like the Federal Medical Stores to the State Medical Stores and to the health facilities.

This method is appropriate in the following situations and these "conditionality's" were challenging in the case of Nigeria at the time of the baseline survey:

a. When reliable data on past use can be collected;

b. Where the demand for health-care services has reached a relatively steady level;

c. When the demands of the health-care system are met by an established and functional supply management system that ensures an uninterrupted supply of narcotic medicines; and

d. When the use of controlled substances is rational.

Caution may be exercised when using the consumption-based method and variants in the following situations:

a. The method does not necessarily improve rational prescribing;

b. In situations of consumption-based variants, calculations centered on quantities requested by trading companies for future sales may be influenced by market dynamics and thus not reflect medical requirements;

c. Long periods of stock out, loss and wastage may reduce the accuracy of the method. Thus, in situations of stock out, computation of average daily consumption is encouraged and this is extrapolated over 365 days for the average annual consumption; and

d. Data collected under this method may be incomplete because of poor stock management, inadequate record keeping or inadequate reporting to the authorities responsible for data collection. Hence it is advisable to collect data over a period of not less than 3 years, across several facility types and a rather high sample size to reduce the impact of the aforementioned.

The detail of this method is described in *Annex 4***.**

Morbidity-based method:

Alternatively, the morbidity-based method could be used in future quantification exercises'. This method estimates the requirements for narcotic medicines based on an assessment of the frequency of health problems (morbidity) and on standardised treatments for these disease conditions. Details of this method are shown in *Annex 5*.

7. FORMS FOR DATA COLLECTION

These are shown in Annex 4. QN 01 is meant to collect data on narcotic medicines from health care facilities while QN 02 is for collection of data on narcotic medicines from retail community pharmacies. The typology for the tools is similarly demonstrated in Annex 4.

Routine collection of data on narcotic medicines can be facilitated through the following process:

- The Federal Ministry of Health (FMOH) and NAFDAC should distribute and receive the appropriate forms – QN 01& QN 02 from facilities through LMCU by the DPS and NAFDAC state offices. These forms should be filled based on records from the medical stores such as disposal of poison book (Form K), stock cards and dangerous drug record book (DDA Form book),
- Expired or wasted medicines should be captured in the "remark" section of the appropriate forms – QN 01 & QN 02,
- Consumption should be captured as quantities issued with the assumption that, all issued drugs including suspensions, syrups and vials are completely used (see typology of research tools in *Annex 3*),
- The completed forms should be returned to the National Coordinator (NC), NPSCMP through DPS and NAFDAC state coordinators on or before end of January for subsequent analysis.

Meanwhile, Forms QN 01 & QN 02 are not meant to replace the standard INCB forms but to complement them. Standard INCB forms must continue to be filled and returned according to laid down protocols

- NAFDAC should continue using INCB's Form B for the estimates for scientific purposes on needs basis (research and clinical trials);
- The completed Form B must be submitted to INCB by the end of June every year.

8. Sources of Data

The quantification process is essentially based on "Good Record Management Practice". Data may be obtained from ledgers of stakeholders (incl. Federal Medical Stores, State Medical Stores, etc) in the drug supply chain management system. Other sources of data may include disposal of poison book (Form K), stock cards and dangerous drug record book (DDA Form book).

Medicine records:

The following are essential for this record: type of narcotic medicines, schedule, quantity received, date of receipt, quantity dispensed daily, dosage form dispensed, total quantity dispensed, quantity loss due to expired product, remaining quantity at the end of the year (stock on hand).

Case records:

This include, unique patient identification, age, sex, weight, type of narcotic medicines administered, schedule, number of treatment episode during the current year, indication or diagnosis, daily posology, daily quantity administered, duration of treatment, among others.

9. STEPS IN QUANTIFICATION

i. Collect data using the appropriate data collection forms QN 01 & QN 02 (Annex 4) from health facilities and retail community pharmacies respectively

ii. Enter data into the data entry template (*Annex 4, sample Table A4.1*)

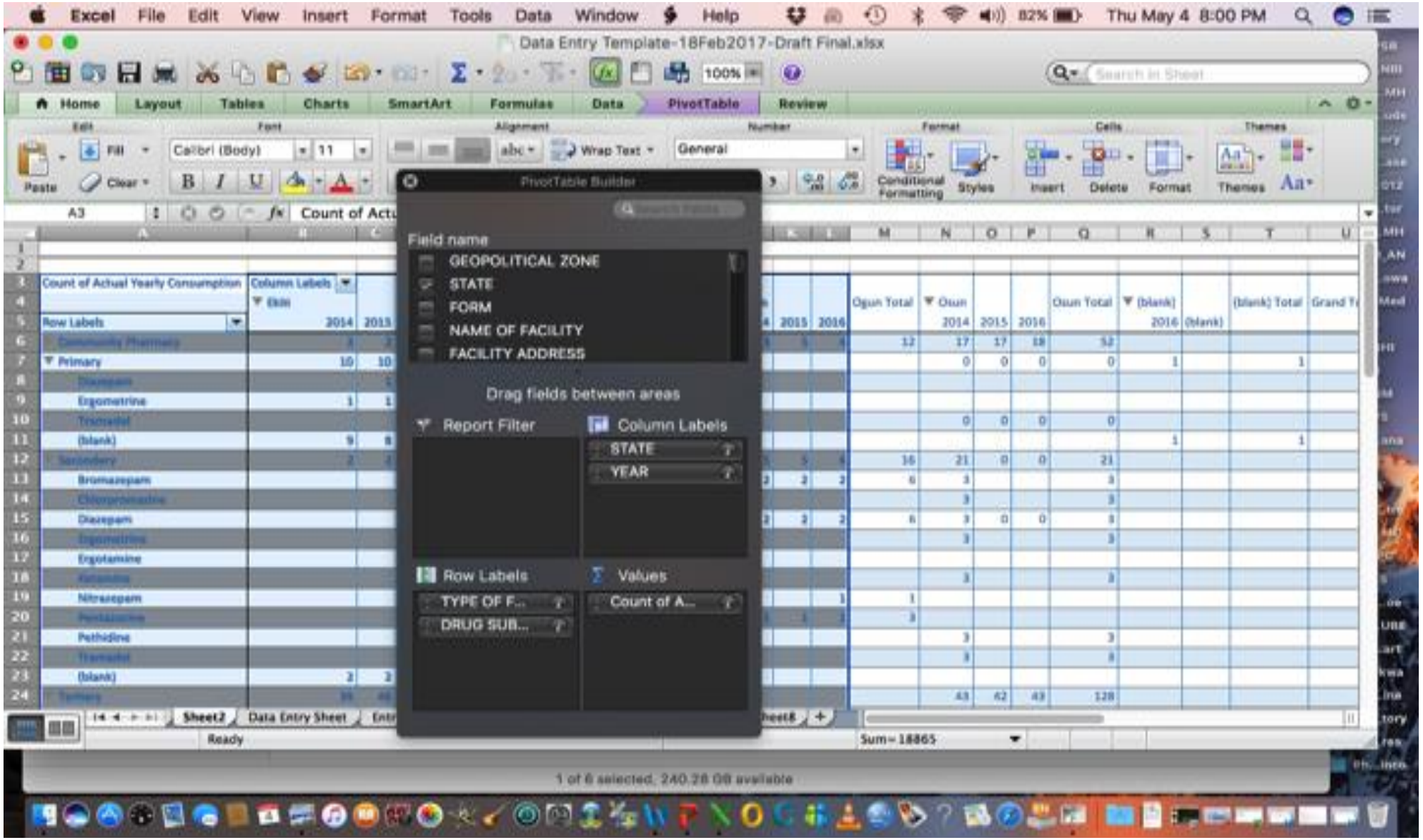
iii. Clean data of any wrong entries

iv. Analyse data using the data entry template in MS Excel (*Tables A4.1 & A4.2 in Annex 4*) and the pivot table as demonstrated below.

Example of Pivot Table

i. Review the estimated results upwards by 10% for unforeseeable events in the future (*Annex 4, Table A4.2*).

ii. Adjust the resultant estimate for observed national trends and for expected upcoming programmes that may require increased narcotic medicines use.


Excel File Edit View Insert Format Tools Data Window Help
Data Entry Template-18Feb2017-Draft Final.xlsx
Home Layout Tables Charts SmartArt Formulas Data PivotTable Review
PivotTable Builder
Field name
GEOPOLITICAL ZONE
STATE
FORM
NAME OF FACILITY
FACILITY ADDRESS
Drag fields between areas
Report Filter
Column Labels
STATE
YEAR
Row Labels
TYPE OF F...
DRUG SUB...
Values
Count of A...
Count of Actual Yearly Consumption
Column Labels
Row Labels
Sheet2
Data Entry Sheet
Ready
Sum=18865
1 of 6 selected, 240.28 GB available

10. DATA COLLECTION FOR SCIENTIFIC PURPOSES

Research institutions and persons engaged in forensic analysis, teaching and research should precisely quantify the narcotic medicines (schedules I, II, III, and IV) they need and send requests to the Directorate of Narcotics and Controlled substances, NAFDAC according to laid down protocols. This process should run concurrently with scheduled surveys for narcotic medicines.

11. DATA COLLECTION FROM DRUG MANUFACTURERS, IMPORTERS AND EXPORTERS

- Manufacturers, importers and exporters should send to the Directorate of Narcotics and Controlled Substances of NAFDAC quantities of narcotic medicines they intend to manufacture, import or export using the prescribed form before the end of March.
- Manufacturers should consider how much stock of narcotic medicines to hold by December31 of the year to which the estimate relates. These stocks refer to the quantities of narcotic medicines to be held in reserve by manufacturers at the end of the year. As a general rule, they should not exceed the requirements for narcotic medicines calculated for 1 year. Stocks must be large enough to provide a safeguard to any breakdown in supply, for example as a result of delays in delivery
- This process should run concurrently with scheduled surveys for narcotic medicines to complement

12. SUBMISSION OF NATIONAL NARCOTIC MEDICINES NEEDS BY NAFDAC TO INCB

- NAFDAC must submit Form B to INCB on or before30 June of the year preceding that to which the estimates apply. NAFDAC may amend the annual estimates, increase or reduce them, as a result of unforeseen changes by furnishing supplementary estimates to INCB (*see Annex 6 for administration of the system of estimates and assessment for controlled drugs*).
- Such amendments should be accompanied by explanations of the circumstances that make the amendment necessary. The INCB examines the assessments, requests explanations when necessary, confirms the estimates, and publishes them considering all countries at the beginning of the year in its technical report on narcotic medicines. Amended estimates are published monthly on INCB's website (*see Annex 6 for administration of the system of estimates and assessment for controlled drugs*).

13. COORDINATION

NAFDAC is essentially a regulatory institution whereas the FMOH is mainly an end user of narcotic medicines among other medicines. Regardless of the schedule of the narcotic medicine, it is recommended that,

- FMOH to coordinate scheduled surveys for narcotic medicines, and
- NAFDAC to coordinate routine returns and request for narcotic medicines following standard protocols.

14. FUTURE ACTIONS

- The guidelines should be reviewed every two years by FMOH and NAFDAC.
- FMOH and NAFDAC to establish an annual budget covering all activities relevant to the quantification of narcotic medicines.
- FMOH and NAFDAC to collaborate with all stakeholders including DPSs, Medical Stores (Federal Central Medical Stores, State Medical Stores and Military/Paramilitary Medical Stores), Health Facilities/Treatment centers, Researchers, Community Pharmacies and Manufacturers about their obligations to provide relevant data for the national quantification of narcotic medicines. FMOH and NAFDAC must provide supportive supervision to develop capacity in generating the needed data.
- FMOH and NAFDAC to designate appropriately qualified staff for the quantification of narcotic medicines. This should be integrated into the established system to avoid creating another vertical job programme to assure sustainability.
- Build capacity through training of personnel at FMOH, SMOH, NAFDAC, Health Facilities/Treatment Centres, Community Pharmacies, Research Institutions and Manufacturing Facilities to use the appropriate tools in collecting the needed data.
- Training manual to be developed by the project consultant to facilitate scale up of training.
- Using TOT approach and the training manual, FMOH and NAFDAC must build capacity among stakeholders through training of personnel across a wide profile. Content of training to include data collection using appropriate tool, data transmission and management as well as analysis.

ANNEX 1: TRAJECTORY IN THE DEVELOPMENT OF THE NATIONAL QUANTIFICATION GUIDELINES

1. In September 2014, as part of the UNODC implemented project, a review and analysis of international, regional and national guidelines on quantification was undertaken by a consultant engaged by the project. This included a review of best practices and international recommendations from INCB and other organizations; as well as policies, work plans and guidelines from Nigeria.
2. In October 2014, due consultations were held through meetings and a workshop with the members of the Technical Working Group (TWG) on control of narcotics, psychotropic substances and precursors for medical, industrial and scientific use in Nigeria. These consultations were in collaboration with FMOH, NAFDAC and UNODC principally to gather information and understand the priorities of the government and stakeholders in the Nigerian context.
3. In November 2014, a second consultant developed the draft guidelines, which was adapted for implementation in the Nigerian context based on the above information and analysis.
4. In February 2015, the draft guidelines were reviewed and revised at a workshop by the members of the TWG on control of narcotics, psychotropic substances and precursors in Nigeria.
5. The estimation tools were field tested at selected health facilities in the country
6. The TWG validated the field-tested estimation tools for inclusion in the Guidelines.
7. In October 2016, the draft Guidelines (including data collection tools) were piloted in selected States in the 6-geopolitical zones of the country namely Gombe, Kano, Oyo, Kwara, Enugu and Edo states to determine its practicability.
8. In November 2016, the pilot of the quantification and estimation exercises' result was reviewed.
9. In March-April 2017, the quantification and estimation exercise were scaled up to include the 36 states & FCT. Also, data collection, analysis and realistic estimates were established.
10. August 2017, The Guidelines for the Quantification of Narcotic Medicines was finalized by the TWG.
11. The final draft of the Guideline for the Quantification of Narcotic Medicines was presented to the FMOH

12. The Ministry obtained approval of the National Council on Health for implementation of the Guidelines by all the 36 states and the Federal Capital Territory
13. The National Guidelines for the Quantification of Narcotic Medicines was published and disseminated.

ANNEX 2: LIST OF NARCOTIC MEDICINES

S. No.	Opioid Medicines	S. No.	Opioid Medicines
1	Codeine Syrup 10.95mg/5ml in 100ml	21	Morphine Tablet 10mg
2	Codeine Syrup 25mg/5ml in 100ml	22	Pethidine Injection 100mg/2ml in 2ml
3	Codeine Syrup 5.7mg/5ml in 100ml	23	Pethidine Injection 50mg/ml in 1ml
4	Codeine Syrup 7.5mg/5ml in 100ml	24	Pethidine Injection 50mg/ml in 2ml
5	Codeine Tablet 100mg	25	Pethidine Tablet 50mg
6	Codeine Tablet 30mg	26	Pholcodeine Syrup 2mg/5ml in 100ml
7	Codeine Tablet 8mg	27	Tramadol Capsule 100mg
8	Dextromethorphan Syrup 10mg/5ml in 100ml	28	Tramadol Capsule 120mg
9	Dextromethorphan Tablet 7mg	29	Tramadol Capsule 200mg
10	Dihydrocodeine Tablet 30mg	30	Tramadol Capsule 50mg
11	Fentanyl Citrate Injection 0.1mg/2ml in 2ml	31	Tramadol Injection 100mg/2ml in 2ml
12	Fentanyl Citrate Injection 0.5mg/10ml in 10ml	32	Tramadol Injection 100mg/ml in 1ml
13	Methadone Suspension 10mg/5ml in 100ml	33	Tramadol Injection 100mg/ml in 2ml
14	Methadone tablet 20mg	34	Tramadol Injection 50mg/ml in 1ml
15	Morphine Injection 10mg/ml in 1ml	35	Tramadol Injection 50mg/ml in 2ml
16	Morphine Injection 15mg/ml in 1ml	36	Tramadol Tablet 100mg
17	Morphine Syrup 10mg/5ml in 500ml	37	Tramadol Tablet 200mg
18	Morphine syrup 5mg/5ml in 100ml	33	Tramadol Tablet 50mg
19	Morphine Syrup 5mg/5ml in 200ml		
20	Morphine Syrup 5mg/5ml in 500ml		

ANNEX 3: DATA COLLECTION TOOLS

Form QN 01: Quantification of Opioid Medicines at Health Facility Level (***This should be completed at the end of the year being reported***)

Consumption-based method and variants

NAME OF FACILITY:								
ADDRESS:								
TYPE OF FACILITY (PRIMARY, SECONDARY, TERTIARY):						**OWNERSHIP (PRIVATE, PUBLIC, ETC)**		
YEAR (eg. 2014, 2015 & 2016):			**REPORTING PERIOD (e.g. Jan 1– Dec 31):**					
	DRUG SUBSTANCE INDICATED (see list below)	**DOSAGE FORM** e.g tab, inj	**STRENGTH** e.g mcg or mg (Indicate total volume of ampoule, vial, bottle, etc)	**QUANTITY** Dispensed for each dosage Form (No. of Tabs, Ampoules.)	**QUANTITY** Dispensed for each Dosage Form in mcg or mg Do not fill	**TOTAL** Quantity of Drug Substance Indicated in grams Do not fill	**PERIOD of Stock Out** For Each Dosage Form in Days	**Remarks (e.g. how much expired, pilfering, etc)**
S/N	**(A)**	**(B)**	**(C)**	**(D)**	**E= C X D**	**F= E (mg) * 10^{-3}**	**(G)**	**(H)**
	Pethidine Hydrochloride	Inj	50mg/1ml (2ml)	500	50,000	**50**	**0**	**Example**
1								
2								
3								
4								
5								

	DRUG SUBSTANCE INDICATED (see list below)	**DOSAGE FORM** e.g tab, inj	**STRENGTH** e.g mcg or mg (Indicate total volume of ampoule, vial, bottle, etc)	**QUANTITY** Dispensed for each dosage Form (No. of Tabs, Ampoules.)	**QUANTITY** Dispensed for each Dosage Form in mcg or mg Do not fill	**TOTAL** Quantity of Drug Substance Indicated in grams Do not fill	**PERIOD of Stock Out** For Each Dosage Form in Days	**Remarks (eg how much expired, pilfering, etc)**
S/N	**(A)**	**(B)**	**(C)**	**(D)**	**E= C X D**	**F= E (mg) * 10^{-3}**	**(G)**	**(H)**
6								
7								
8								
9								
10								
FOOT NOTE:		• [illegible] out columns E & F • Column C should indicate the strength per tablet, ampoule, vial or entire bottle of syrup or suspension • Column D will be obtained from Stock Card and by Physical Count						
Form Completed by (name and position): Phone number:			**Submission Approved by** (name and position): Phone number:			**Date Form submitted:**		

Any additional useful information gathered from the field:

Opioid medicines of interest: Pethidine, Morphine (Tab, Inj, Oral Syr), Fentanyl, Methadone, Oxycodone, Hydromorphone, Hydrocodone, Codeine, Dihydrocodeine, Methadone, Tramadol (Segregation into Schedules (I, II, III) of drugs will be done at the level of analysis). This list is not exhaustive but simply a guide.

Pulverized morphine sulphate (powder) should be captured in the appropriate strength as drug in stock though its consumption is only captured in the reconstituted form e.g. syrup.

Form QN 02: Quantification of Opioid Medicines in **Community Pharmacies (*This should be completed at the end of the year being reported***)

Method: Consumption-based method and variants

NAME OF FACILITY:								
ADDRESS:								
OWNERSHIP (PRIVATE, PUBLIC, ETC):								
YEAR (eg. 2014, 2015 & 2016):			**REPORTING PERIOD (e.g. Jan 1– Dec 31):**					
	DRUG SUBSTANCE INDICATED (see list below)	**DOSAGE FORM** e.g tab, inj	**STRENGTH** e.g mcg or mg (Indicate total volume of ampoule, vial, bottle, etc)	**QUANTITY** Dispensed for each dosage Form (No. of Tabs, Ampoules.)	**QUANTITY** Dispensed for each Dosage Form in mg **Do not fill**	**TOTAL** Quantity of Drug Substance Indicated in grams **Do not fill**	**PERIOD of Stock Out** For Each Dosage Form in Days	**Remarks (eg how much expired, pilfering, etc)**
S/N	**(A)**	**(B)**	**(C)**	**(D)**	**E= C X D**	**F= E (mg) * 10^{-3}**	**(G)**	**(H)**
	Pethidine Hydrochloride	Inj	50mg/1ml (2ml)	500	50,000	**50**	**0**	**Example**
1								
2								
3								
4								
5								
6								

	DRUG SUBSTANCE INDICATED (see list below)	**DOSAGE FORM** e.g. tab, inj	**STRENGTH** e.g. mcg or mg (Indicate total volume of ampoule, vial, bottle, etc)	**QUANTITY** Dispensed for each dosage Form (No. of Tabs, Ampoules.)	**QUANTITY** Dispensed for each Dosage Form in mg **Do not fill**	**TOTAL** Quantity of Drug Substance Indicated in grams **Do not fill**	**PERIOD of Stock Out** For Each Dosage Form in Days	**Remarks (eg how much expired, pilfering, etc)**
S/N	**(A)**	**(B)**	**(C)**	**(D)**	**E= C X D**	**F= E (mg) * 10^{-3}**	**(G)**	**(H)**
7								
8								
9								
10								
11								
12								
13								
FOOT NOTE:		• [redacted] out columns E & F • Column C should indicate the strength per tablet, ampoule, vial or entire bottle of syrup or suspension • Column D will be obtained from Stock Card and by Physical Count						

Form Completed by (name and position): Phone number:	**Submission Approved by** (name and position): Phone number:	**Date Form submitted:**

Any additional useful information gathered from the field:

Opioid medicines of interest: Pethidine, Morphine (Tab, Inj, Oral Syr), Fentanyl, Methadone, Oxycodone, Hydromorphone, Hydrocodone, Codeine, Dihydrocodeine,Methadone, Tramadol (Segregation into Schedules (I, II, III) of drugs will be done at the level of analysis). This list is not exhaustive but simply a guide.

Pulverized morphine sulphate (powder) should be captured in the appropriate strength as drug in stock though its consumption is only captured in the reconstituted form eg syrup.

Typology of instruments used for the quantification of opioid medicines

Instrument Code	Title / Purpose	Comment/s
QN 01	Quantification of opioid medicines at health facility level	Consumption-based method and variants. Drug substance should be a population of all opioids ever used in the institution in the last 3 years. Dosage form should capture as tablet, injection, syrup, etc. Strength should be captured as per tablet, total strength per ampoule or vial or bottle and indicate volume. Quantity dispensed per each dosage form captures physical count of tablet, ampoule, vial or bottle dispensed assuming all were used by the patient. Quantity dispensed for each dosage form in mcg, mg, etc is a computed value and should be left out. Period of stock out for each dosage form is absolutely important to determine average daily consumption hence yearly consumption for dosage forms with missing data.
QN 02	Quantification of opioid medicines in community pharmacies	Consumption-based method. The drug substance includes all opioid medicines used in the facility over the last 3 years. Dosage form should be captured as tablet, injection, syrup, etc. The drug strength should be recorded as mcg/mg per tablet or total strength per ampoule, syrup or bottle indicating volume of ampoule, vial or bottle. The total number of units dispensed per dosage form describes the physical number of tablets, ampoules, vials or bottles dispensed. Total quantity in grams is a computed value and should not be filled.

ANNEX 4: CONSUMPTION-BASED METHODS AND VARIANTS

The consumption-based method and its variants are necessarily based on past health-care demands for narcotic medicines. In situations where the past use of narcotic medicines is stable, future requirements can be estimated by averaging the amounts consumed in recent years and adding a margin for unforeseeable increases. A variant of this method may also be applied when patterns of past use of controlled substances show a clear upward or downward trend and when known explanations for such trends allow for the prediction of future changes in use[1].

Data collection:

The following procedure should be followed in collecting data:

1: Identify the stakeholders in the narcotic medicines supply management system including manufacturers and importers and health-care system like health facilities (hospitals) and community pharmacies who handle narcotic medicines.

2: Obtain the quantities of narcotic medicines used, requested and imported during the previous three years, as a minimum (see data collecting tools in Annex 4).

3: Identify new situations that require additional quantities of narcotic medicines (e.g. Pain Free Hospital Initiative – PFHI project, establishment of new Hospices and Palliative Care Centres, and population size changes).

Calculation procedure:

Here is an example showing how to compute a country's morphine requirement:

Example: Calculating the morphine requirement of Nigeria for 2017.

Step 1: (a) Average the data (from step 2 of the data collection procedure described above) from the previous three years. Records kept by the competent authorities indicate that morphine use in Nigeria for the three-year period 2014-2016 was as follows:

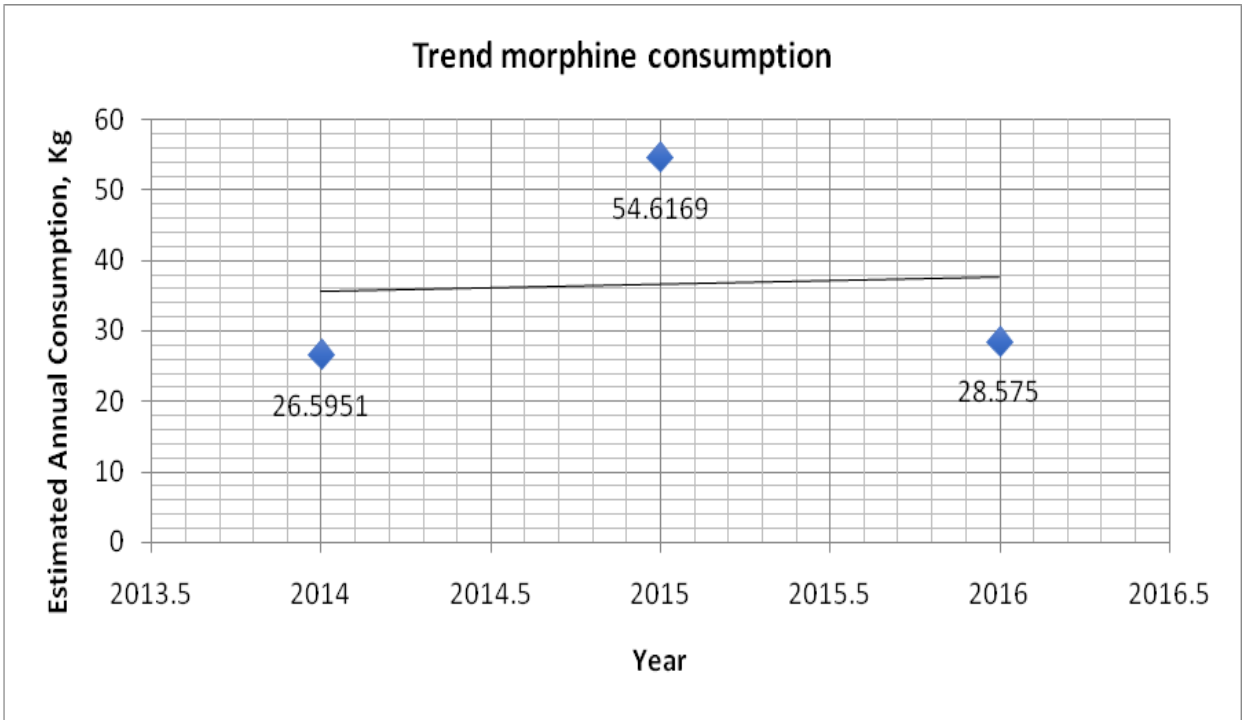
Year	Morphine consumption (Kg)
2014	10.53
2015	15.78
2016	74.04

The average for the period under study is calculated as follows: (10.53kg + 15.78kg + 74.04kg)/3 = 33.45 kg

[1]INCB & WHO (2012). Guide on Estimating Requirements for Substances under International Control

(b) Increase the calculated average by 10 per cent to allow for unforeseeable circumstances, as follows: 33.45 kg + 3.345 kg = 36.795 kg

Step 2: Add to the value of the result from step 1 (b) of the calculation procedure the additional quantities mandated by changes in circumstances (from step 3 of the data collection procedure described above).



The competent authorities have observed a slight increase in the consumption of morphine in the last 3 years (see graph above) due to the impact of the PFHI and the construction of 2 new Hospices and Palliative Care Centres. The estimated annual increase in morphine consumption due to the programme impact is computed to be 10kg. Therefore, this quantity should be added to the value from step 1 (b) of the calculation procedure, as follows: 36.795 kg + 10 kg = 46.795 kg.

This is the estimated morphine requirement for Nigeria in 2017.

Table A4.1: Data Entry Template
Example of partial data entry template showing calculation of actual yearly consumption (read details in survey report)

DRUG SUBSTANCES DOSAGE FORM STRENGTH	TOTAL STRENGTH IN FIGURES [e.g. 100= 50mg/ml (2ml)]	QUANTITY DISPENSED FOR EACH DOSAGE FORM (No. of Tabs, Ampoules.)	PERIOD OF STOCK OUT FOR EACH DOSAGE FORM IN DAYS	QUANTITY Dispensed for each Dosage Form in mg	TOTAL Quantity of Drug Substance Indicated in grams	# DAYS the drug was available	Actual Daily Consumption	Actual Yearly Consumption
Codeine Syrup 10.95mg/5ml in 100ml	219	14	77	3066	3.066	288	0.0106	3.8857
Tramadol Injection 50mg/ml in 2ml	100	2	0	200	0.2	365	0.0005	0.2000
Tramadol Capsule 50mg	50	6865	0	343250	343.25	365	0.9404	343.2500
Tramadol Injection 100mg/ml in 1ml	100	80	0	8000	8	365	0.0219	8.0000
Dihydrocodeine Tablet 30mg	30	500	0	15000	15	365	0.0411	15.0000
Tramadol Injection 50mg/ml in 1ml	50	2000	0	100000	100	365	0.2740	100.0000
Tramadol Injection 50mg/ml in 2ml	100	1000	0	100000	100	365	0.2740	100.0000
Tramadol Tablet 50mg	50	3000	0	150000	150	365	0.4110	150.0000
Fentanyl Citrate Injection 0.5mg/10ml in 10ml	0.5	100	0	50	0.05	365	0.0001	0.0500
Morphine Injection 10mg/ml in 1ml	10	200	0	2000	2	365	0.0055	2.0000
Morphine Injection 15mg/ml in 1ml	15	570	0	8550	8.55	365	0.0234	8.5500
Morphine Tablet 10mg	10	910	0	9100	9.1	365	0.0249	9.1000
Pethidine Injection 100mg/2ml in 2ml	100	239	0	23900	23.9	365	0.0655	23.9000
Pethidine Tablet 50mg	50	1110	0	55500	55.5	365	0.1521	55.5000

Table A4.2: Example showing calculation of narcotic medicines over a 3-year period with 10% mark-up

Drugs	Minimum estimate: projection from state quantities (A)					Maximum estimate: projection using total numbers of health facilities across country (B)				
	Estimated Consumption (kg)			Estimated annual national consumption for each Drug strength in Kg	Annual consumption with 10% Mark up in Kg	Estimated Consumption (kg)			Estimated annual national consumption for each Drug strength in Kg	Annual consumption with 10% Mark up in Kg
	2014	2015	2016			2014	2015	2016		
Opioid Medicines										
Codeine Syrup 10.95mg/5ml in 100ml	250.6826	242.8450	195.1850	256.7750	282.4525	2747.7418	2425.2191	2240.7453	2478.5558	2726.4114
Codeine Syrup 25mg/5ml in 100ml	2.8744	2.0317	1.9996	2.3019	2.5321	117.2334	82.8638	81.5537	93.8836	103.2720
Codeine Syrup 5.7mg/5ml in 100ml	42.5490	61.2802	112.5033	72.2412	79.4654	1079.2734	1555.1548	952.9775	1099.0500	1208.9550
Codeine Syrup 7.5mg/5ml in 100ml	0.6853	0.7929	0.9722	0.8954	0.9849	27.9497	37.7215	42.3435	40.5562	44.6118
Codeine Tablet 100mg	1.3500	0.6750	0.1350	0.7200	0.7920	34.2600	17.1300	3.4260	18.2720	20.0992
Morphine Injection 10mg/ml in 1ml	0.3638	0.3283	0.3272	0.3586	0.3944	2.3456	1.5769	1.4729	1.7938	1.9732
Morphine Injection 15mg/ml in 1ml	0.3913	0.1892	0.7234	0.5310	0.5841	0.8855	0.3602	1.7324	0.9871	1.0858
Morphine Syrup 10mg/5ml in 500ml	0.0029	1.0132	4.5990	2.8090	3.0899	0.1222	12.1583	55.1880	22.4895	24.7384

Morphine syrup 5mg/5ml in 100ml	0.0560	0.0660	0.0051	0.0610	0.0671	1.1757	0.9255	0.2127	0.8901	0.9791
Morphine Syrup 5mg/5ml in 200ml	0.6177	1.4706	2.9679	1.7285	1.9014	2.9440	5.7695	14.5932	7.5336	8.2869
Morphine Syrup 5mg/5ml in 500ml	2.9619	6.0126	7.1565	6.3799	7.0179	10.5264	15.7829	74.0430	73.3533	80.6886
Morphine Tablet 10mg	0.1050	0.1906	0.0574	0.1884	0.2073	6.2278	0.4320	0.4090	6.3868	7.0254
Pethidine Injection 100mg/2ml in 2ml	4.4506	2.0332	1.6211	4.1200	4.5319	82.7838	11.1887	5.3871	83.7332	92.1066
Pethidine Injection 50mg/ml in 1ml	0.1000	2.7239	0.0000	1.4119	1.5531	4.2000	114.4030	0.0000	59.3015	65.2316
Pethidine Injection 50mg/ml in 2ml	9.1048	1.7763	0.8650	5.2489	5.7738	25.3339	15.1053	21.9624	24.0741	26.4815
Pethidine Tablet 50mg	0.0070	0.2653	0.5518	0.4544	0.4998	0.2940	0.5212	1.2847	0.8617	0.9478

ANNEX 5: MORBIDITY-BASED METHOD

The morbidity-based method uses data on the frequency of health problems (morbidity) and a standardised guide on how these health problems will be treated to calculate the requirements for narcotic medicines. The quantity of drugs recommended as the standard treatment for each health problem multiplied by the number of treatment episodes for that health problem provides the quantity required. The sum of the requirements calculated for each health problem treated with a particular drug substance provides the total requirement for the unique drug --- narcotic.

Data collection

The following steps should be taken when collecting data:

1. Populate a list of disease conditions to be treated with a unique narcotic medicine. This can be done through a review of hospital records including patient information data or through qualitative surveys like Focus Group Discussion (FGD) or In-depth Interviews of Key Informants (KII).
2. Establish the average quantity of the unique narcotic medicine required for a standard course of treatment for each disease condition. If nationally accepted treatment schedules for the disease conditions are not available, they should be developed in consultation with experts, taking into account authoritative treatment guidelines, such as those from WHO, or authoritative medical literature and accepted medical practice in a given country. The standard treatment schedules should specify, for each disease condition, the average dose of the unique narcotic medicine, the number of doses per day and the duration of the treatment.
3. Estimate the number of treatment episodes for each disease condition

Data on the frequency of disease conditions can be collected from centrally compiled patient morbidity registries at the State or Federal Ministry of Health. Alternatively, morbidity profiles of sample facilities can be used and the calculated requirement extrapolated to other like-facilities in the same state. If the morbidity data in sample facilities are not of adequate quality, a special study may be required to collect more complete and detailed information[2].

[2]INCB & WHO (2012). Guide on Estimating Requirements for Substances under International Control.

Calculation procedure[3]

The following steps should be taken when calculating the quantity of a narcotic medicine required for each disease condition:

1. Multiply the quantity of the narcotic medicine required for a standard course of treatment (data from step 2 of the data collection procedure) by the number of treatment episodes of a disease condition (data from step 3 of the data collection procedure);

2. Repeat step 1 of the calculation procedure for each disease condition included in the quantification;

3. If a narcotic medicine is used to treat more than one disease condition which is quite often the case, add up the various quantities calculated to obtain the total requirement.

The example below shows how the calculation procedure should be applied:

The competent authorities in Nigeria want to calculate the annual requirement for morphine. In Nigeria, morphine is used for the treatment of moderate to severe pain in cancer and AIDS patients. There are no nationally accepted treatment norms that indicate the quantity of morphine that can be expected to be used by cancer and AIDS patients in the course of their treatment. Therefore, the competent authorities work with national experts in palliative care to identify an average quantity from an authoritative source in medical literature.

The experts recommend using recent cancer and AIDS mortality data (or morbidity data, where available) and applying the following formula: at the end of their lives, 80 per cent of cancer patients and 50 per cent of AIDS patients require an average of 60-75 mg of morphine per day for 90 days, so the mid-point of 67.5 mg per patient should be used. National morbidity estimates for the numbers of advanced cancer and AIDS patients are not available in Nigeria. Therefore, the competent authorities decide to use the number of late-stage cancer and AIDS patients in all health-care facilities that provide care to such patients.

The calculation for the morphine requirement for late-stage cancer patients (80 per cent of whom are estimated to need morphine at an average dose of 67.5 mg per day for 90 days) is shown in the Table below (A5.1).

[3]INCB & WHO (2012). Guide on Estimating Requirements for Substances under International Control

Table A5.1.: Calculating the morphine requirement for late-stage cancer patients in Nigeria

Sample facility	Number of late-stage cancer patients	Total number of facilities in country	National approximation of late-stage cancer patients for each type of sample facility	80 per cent of patients who need pain treatment	Average amount of morphine per patient over a 90-day standard course of treatment	Total quantity of morphine consumed by all late-stage cancer patients
National referral hospital with palliative care unit	1000	1	1000	800	6075mg (0.006075kg)	4.86kg
Regional hospital with palliative care unit	500	5	2500	2000	6075mg (0.006075kg)	12.15kg
Hospice with home-based care	300	10	3000	2400	6075mg (0.006075kg)	14.58kg
Total				**5200**		**31.59kg**

The calculation of the morphine requirement for late-stage AIDS patients (50 per cent of whom are estimated to need morphine) is shown in Table A6.2.

Table A5.2: Calculating the morphine requirement for late-stage AIDS patients in Nigeria

Sample facility	Number of late-stage AIDS patients	Total number of facilities in country	National approximation of number of late-stage AIDS patients for each type of sample facility	Number of patients who need pain treatment (50 per cent)	Average amount of morphine per patient in standard course of treatment	Total quantity of morphine consumed by all late-stage AIDS patients
National referral hospital with palliative care unit	1200	1	1200	600	6075mg (0.006075kg)	3.65 kg
Regional hospital with palliative care unit	800	5	4000	2000	6075mg (0.006075kg)	12.15 kg
Hospice with home-based care	500	10	5000	2500	6075mg (0.006075kg)	15.19 kg
Total				**5100**		**30.99 kg**

Therefore, the total annual requirement for morphine for late-stage cancer and AIDS patients would be calculated as follows: 31.59 kg + 30.99 kg = 62.58 kg. It should be noted that these figures do not comprise requirements for morphine to treat acute pain from other causes such as heart attacks, bone fractures etc. Therefore, these need to be added using similar or other methods **{***adapted from INCB & WHO (2012) "Guide on estimating requirements for substances under international control"***}**.

ANNEX 6: THE ADMINISTRATION OF THE SYSTEM OF ESTIMATES AND ASSESSMENTS FOR CONTROLLED DRUGS: NARCOTIC MEDICINES, PSYCHOTROPIC SUBSTANCES AND PRECURSORS

Key steps in the administration of estimates and assessments [4]

	Estimates for narcotic drugs	Assessment for psychotropic substances	Estimates for precursors
Form used	B	B/P	D
Frequency of submission	Once a year	At least once every three years	Once a year
Submission deadline	30 June of the previous year	Any time	30 June of the previous year
Confirmation by INCB required	Yes	No	No
Validity	One year	Until amended, but preferably three years	Until amended, but preferably one year
Related publication and information source	INCB technical publication and website	INCB technical publication and website	INCB precursors report and website
Amendments possible	Yes, throughout the year	Yes, any time	Yes, throughout the year
Forms for amendments	Supplement to form B	B/P	Official correspondence from Government
Publication of amendments	Monthly on INCB website and quarterly in print	Monthly on INCB website and quarterly in print	As required, on INCB website

[4]INCB & WHO (2012). Guide on Estimating Requirements for Substances under International Control

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